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National Aeronautics and Space Administration Office of Biological and Physical Research Washington, DC 20546-0001

# NASA Research Announcement Soliciting Ground-based Research Proposals

## **Biomedical Research and Countermeasures Program**

- 1. Independent Investigator Research Projects, or
- 2. Research Projects for a Research Team of the National Space Biomedical Research Institute

A Research Announcement for the NASA Office of Biological and Physical Research

Notices of Intent Due: May 15, 2003
Proposals Due: July 15, 2003

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## NASA Research Announcement: Ground-based Research Proposals

## **Biomedical Research and Countermeasures Program**

- 1. Independent Investigator Research Projects or
- 2. Research Projects for a Research Team of the National Space Biomedical Research Institute

## **Summary and Supplemental Information**

NASA's new Vision for the 21<sup>st</sup> century is:

To improve life here,

To extend life to there,

To find life beyond.

The Office of Biological and Physical Research's (OBPR) contribution to the Agency is to realize this Vision, written as a Mission Statement, that motivates our research on the ISS and is the framework for the activities of OBPR:

Humans will extend the exploration of space. To prepare for and hasten the journey, OBPR must answer these questions through its research:

- How can we assure the survival of humans traveling far from Earth?
- What must we know about how space changes life forms, so that humankind will flourish?
- What new opportunities can our research bring to expand our understanding of the laws of nature and enrich lives on Earth?
- What technology must we create to enable the next explorers to go beyond where we have been?
- How can we educate and inspire the next generations to take the journey?

OBPR is developing a Research Plan that will provide a top-level description of the direction that the Enterprise will take to answer these questions and fulfill its mission. The OBPR Research Plan can be accessed at: <a href="http://spaceresearch.nasa.gov/">http://spaceresearch.nasa.gov/</a>

This National Aeronautics and Space Administration (NASA) Research Announcement (NRA) solicits ground-based proposals for the Biomedical Research and Countermeasures (BR&C) Program. The BR&C Program sponsors research that will lead to the development of countermeasures against the negative effects of space flight on humans. Sponsored research may

be performed at "Countermeasure Readiness Levels" (CLRs) from basic research (CRLs 1-3) through evaluation and validation (CRLs 7 & 8). Applicants should refer to Figure 1 in Appendix A for a detailed description of the CRLs. Each applicant must identify what CRL their application addresses. This NRA solicits research proposals for either **independent investigator research projects** (see Appendix B for details), or proposals for the opportunity to become a **member of an integrated countermeasure development team** of the National Space Biomedical Research Institute (NSBRI) (see Appendix C for details). Please note that proposals for the NSBRI Radiation Effects team and independent investigator research projects in radiation **are not** being solicited in this NRA. Proposals that synergistically bridge multiple disciplines for the purpose of modeling the effects of microgravity on the human body to aid in the development and testing of countermeasures, or to develop technologies that enable research in one or more NSBRI research areas are strongly encouraged.

Applicants must determine if their proposed research is best suited to be conducted independently or as part of an integrated research team of the NSBRI. **Do not submit the same research proposal to both opportunities**.

The Biomedical Research and Countermeasures Program is interested in supporting independent investigator research projects in CRL range 1-7 with a majority of the funded tasks residing in the lower CRL range. The NSBRI is primarily interested in supporting research, in the CRL range of 3-7, that will participate as part of a countermeasure development team focused on advancing the research towards an applied intervention that can be evaluated and validated by the Countermeasure Evaluation and Validation Project (CRL 7 & 8).

NASA investigators use the space environment to increase knowledge of biological and medical processes, to provide the biomedical foundation in support of the International Space Station and exploration beyond low Earth orbit, and to enrich life on Earth through the transfer of new space technology, medicine, and fundamental knowledge. This research supports NASA's mission through the Office of Biological and Physical Research (OBPR). All respondents to this NRA are strongly encouraged to promote general scientific literacy and public understanding of life sciences, the space environment, and the OBPR programs through formal and informal education opportunities. Where appropriate, supported investigators will be required to produce, in collaboration with NASA, a plan for communicating their work to the public.

#### In this NRA,

- Appendix A provides an introduction and overview to the goals, objectives, and implementation strategies of the BR&C Program.
- Appendices B and C contain descriptions of the two opportunities, and specific instructions for submitting a notice of intent (NOI) and instructions for proposal submission.
- Appendix D contains copies of the certifications required to be followed with any signed application.
- Appendix E contains the standard Instructions for Responding to NASA Research Announcements.
- Appendix F provides sample copies of the forms that must be used when preparing the application. Please note that Forms A-E are only required for Independent Investigator

Research Projects applications. Form F is required for Independent Investigator Research Projects and NSBRI Research Team applications.

The BR&C Program and the NSBRI share scientific and educational goals to fund research that will result in the delivery of health-related countermeasures for astronauts. NASA is committed to maintaining a strong, openly competitive, peer-reviewed research program. Proposals submitted in response to this NRA must address the research emphases described in this Announcement. Those that do not will be returned. **This NRA does not request proposals for flight research**. **Proposals that require flight resources will be returned to the proposer without being reviewed.** Other NRAs calling for focused research or utilization of unique resources may be issued throughout the year.

Proposals for individual investigator grants selected by NASA will be funded incrementally as grants for activities lasting up to four years, pending satisfactory progress. Proposals selected by the NSBRI will be funded as subawards by the NSBRI for activities lasting up to four years. The funding duration will depend on proposal requirements, review panel recommendations, and continuing progress of the activity. All proposals will be evaluated for overall scientific and technical merit by independent peer review panels. Relevance to NASA's programmatic needs and goals will be evaluated by NASA. Relevance to the NSBRI's programmatic needs and goals will be evaluated separately by the NSBRI. Final selection will be coordinated between the Bioastronautics Research Division at NASA Headquarters and the NSBRI to ensure programmatic balance and to eliminate duplicate efforts. Funds are not currently available for awards under this NRA. The government's obligation to make award(s) is contingent upon the availability of appropriated funds from which payment can be made and the receipt of proposals that the government determines are acceptable for award under this NRA. The total annual cost for ground research should not exceed \$450,000. NASA and the NSBRI do not provide separate funding for direct and indirect costs; thus, the amount of the award requested is the total of all costs submitted in the proposed budget. It is planned for selections to be announced by December 15, 2003, and awarded shortly thereafter.

<u>Inclusion of Women and Minorities in Research Involving Human Subjects</u> – NASA and the NSBRI have adopted the NIH policy regarding this matter. Women and members of minority groups and their subpopulations must be included in NASA-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research.

Participation in this NRA is open to all categories of organizations, industry, educational institutions, other nonprofit organizations, NASA laboratories, and other agencies of the U.S. government. NASA will not fund non-U.S. institutions. The NSBRI accepts and reviews proposals from foreign applicants, but potential foreign applicants should note that, normally, the country of origin, not the NSBRI, will fund applications from non-U.S. organizations. Potential foreign applicants should coordinate their application with both the NSBRI and the appropriate funding agency in their own country.

A Notice Of Intent (NOI) to propose is requested by May 15, 2003. Proposals must be submitted by July 15, 2003, 5:00 p.m. Eastern Time (see Appendices B and C of this NRA for specific instructions for these activities).

The following items apply only to this NRA:

**Solicitation NRA Identifier: NRA 03-OBPR-04** 

**Number of Copies Required:** Original + 20 paper copies for the non-

**NSBRI** submissions; electronic proposals

for the NSBRI submissions

May 15, 2003 **Notices of Intent Due: Proposals Due:** July 15, 2003 **Selection Announcement: December 15, 2003** 

**Funding Begins:** Approximately 30-90 days following

notification of selection

**Selecting Officials:** For individual BR&C proposals:

**Director, Bioastronautics Research** 

Division, Office of Biological and Physical

Research, NASA Headquarters

For NSBRI proposals: Director, National **Space Biomedical Research Institute** 

Additional information about the BR&C Program and independent investigator proposals is available from

> David L. Tomko, Ph.D. NASA Headquarters, Code UB

Washington, DC 20546-0001 Telephone: 202-358-2211

Fax: 202-358-4168

Email: dtomko@nasa.gov

Information about the NSBRI and its existing research teams is available from

Jeffrey P. Sutton, M.D., Ph.D.

Director, National Space Biomedical Research Institute

One Baylor Plaza, NA-425 Houston, TX 77030-3498 Telephone: 713-798-7412

Fax: 713-798-7413

Email: director@www.nsbri.org

All prospective proposers to this NRA are advised that the highest priority in all of NASA's programs is given to safety and mission assurance, occupational health, environmental protection, information technology, export control, and security. NASA's safety priorities are to protect (i) the public, (ii) astronauts and pilots, (iii) the NASA workforce (including employees working under NASA instruments), and (iv) high-value equipment and property. All proposals submitted in response to this solicitation are expected to comply with this policy.

Grants Office points of contact will be identified in selection letters. This NRA will be updated and issued annually and is NASA's primary means of obtaining ground-based biomedical research proposals from the life sciences community. This NRA is restricted to the programs named above and described in detail in the Appendices. Potential investigators should read with care the program descriptions that are of interest, and focus their proposals on the specific research emphases defined in this NRA.

Your interest and cooperation in participating in this effort is appreciated.

Original signed by

Mary E. Kicza Associate Administrator Office of Biological and Physical Research

## **Background Information**

## Opportunities for Ground-based Research in the Biomedical Research and Countermeasures Program

### I. Introduction

This NASA Research Announcement (NRA) is a consolidated NASA solicitation for research proposals in support of the goals and objectives of the NASA Office of Biological and Physical Research (OBPR). Ground-based research is solicited for conduct by the Biomedical Research & Countermeasures (BR&C) Program. Proposers may apply for a grant as an independent investigator, or as a member of one of the research teams of the National Space Biomedical Research Institute (NSBRI).

The goals of this program are to

- develop an understanding of the physiological mechanisms responsible for space-flightrelated biomedical and behavioral changes in humans in support of countermeasure development;
- develop countermeasures that allow humans to live and work in microgravity for long durations, minimize the risks in readapting to gravity, and optimize crew safety, well-being, and performance; and
- identify, characterize, and mitigate (prevent and reduce) health, environmental, and other operational human medical risks associated with space exploration.

The BR&C Program is responsible for sponsoring research that will lead to development of practical health-related methods for the prevention, diagnosis, treatment, and/or rehabilitation of humans who live and work in microgravity. It also responds directly to the requirements, approved by the Office of the Chief Health and Medical Officer, which deal with the health and safety of human space travel (see *Guidance for NASA Medical Board Procedures*, Bibliographic reference #8 of Appendix A).

The NSBRI is a NASA-initiated and -funded private, non-profit research consortium charged by NASA with developing biomedical countermeasures for potential health problems that could occur in astronauts either during long-duration space flight or on their return to Earth. The NSBRI's current program consists of approximately 90 research and technology projects organized into 11 research teams.

It is critical for investigators to read carefully <u>all</u> of the instructions in this NRA. All proposals will undergo peer review using similar processes and procedures, but procedures and forms for proposal submission differ for the different programs and elements, and the

eventual funding of selected proposals will differ for the different types of awards. Programmatic balance is maintained by the selecting official(s) for the program.

The research programs described in this NRA support the utilization of specialized NASA ground-based facilities and the development of special technologies required in the pursuit of its research goals. Investigators can access NASA specialized ground-based facilities for their research. Please refer to the *Space Life Sciences Ground Facilities Information Package* for instructions on how to incorporate the use of these facilities into a proposal is online at <a href="http://research.hq.nasa.gov/code\_u/nra/current/NRA-03-OBPR-04/index.html">http://research.hq.nasa.gov/code\_u/nra/current/NRA-03-OBPR-04/index.html</a>.

This NRA does not request proposals for flight research. Proposals that require flight resources will be returned to the proposer without being reviewed. It is important that the proposer read all instructions in this NRA carefully, as many of the programmatic emphases are different from those appearing in previous NRAs. In addition, each Appendix includes guidelines, requirements, and instructions for preparing and submitting proposals, and defines the administrative policies governing the particular components described in this NRA.

## II. Critical Path Roadmap (CPR)

In order to identify and make publicly known the biomedical risks of space flight, and the research questions that must be answered to reduce those risks, NASA has developed the Critical Path Roadmap (CPR). The CPR is an interdisciplinary tool to assess, understand, mitigate, and manage the risks to humans that are associated with long-term exposure to the space environment. It assumes an overarching strategy that integrates requirements, risks, risk factors, critical questions, tasks, deliverables, and risk mitigation with the intent of directing biomedical research in support of human space flight, especially human missions of exploration. The CPR is based in part on recommendations from internal NASA experts, NSBRI scientists, advisory committees representing the United States science community, task forces, and published reports such as the National Research Council (NRC) Space Studies Board's "A Strategy for Research in Space Biology and Medicine in the New Century;" the Aerospace Medical Advisory Committee; the NASA Task Force on Countermeasures; the International Space Life Sciences Working Groups publications on Radiation, Bone, Muscle, Cardiovascular, Human Factors, and Neuroscience Workshops; and the NASA Medical Policy Board Document.

The ultimate goal of the CPR is to protect the health and safety of space flight crews by allowing NASA and the community of scientists to better define and focus the research that is required for development and validation of operational health care "deliverables" for the prevention, treatment, and rehabilitation of space flight changes and of appropriate habitation and medical care systems.

The current CPR identifies 55 risks and 250 critical questions. A more extensive overview, as well as a list of all the risks and critical questions for the CPR, should be reviewed by potential investigators at <a href="http://criticalpath.jsc.nasa.gov/">http://criticalpath.jsc.nasa.gov/</a>

The proposer must examine and understand the CPR, and specify in their proposal the rationale and evidence underlying which risks and critical questions their proposed research will answer. An example is shown in Table I below, and the blank form (Form F) can be found in Appendix F. A similar assessment will be performed by NASA and the NSBRI to understand how the proposed research addresses the CPR risks and critical questions. Proposals that do not identify what CPR risks and questions are being addressed by the research will be returned to the proposer without review.

The Biomedical Research and Countermeasures (BR&C) Program utilizes annual and final reports to assess progress relative to stated research objectives and hypotheses as declared in the original grant proposal by the Principal Investigator. It is critical that the reports indicate how the investigation relates to critical questions outlined in the CPR. It must be understood by proposal authors that reporting of progress on an annual basis shall be required and shall be linked to CPR risks and critical questions. In addition, the final report shall address the entire scope of the project rather than the final year and shall be linked to CPR risks and critical questions.

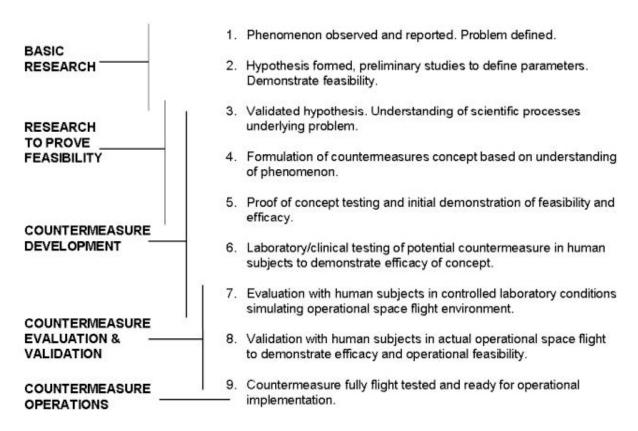
TABLE I EXAMPLE ONLY – Complete Form F in Appendix F for specific proposal

Hypotheses	Risk Number (from Critical Path Roadmap)	Critical Question Number (from Critical Path Roadmap)	Critical Question (from Critical Path Roadmap)	Specific Aim
The combined effects of hypergravity (simulating launch and landing) and bedrest (simulating space flight) along with associated physical and psychological stress will decrease virus specific cellular immunity and reactivate latent herpes viruses.	Risk #22 Immunodeficiency, Infections	7.03	Do factors associated with flight (stress, environment, micro-gravity, nutritional status, radiation) affect humoral or cell mediated immune function, nonspecific immunity, mucosal immunity, or immune surveillance capabilities of crewmembers in a manner that exposes them to unacceptable medical risk (disease, allergy, delayed wound healing)?	#1: Assess stress levels utilizing measures of biochemical and psychological stress.  #2: Determine virus specific T-lymphocyte immunocompetence.
	Risk #22 Immunodeficiency, Infections	7.04	Do factors associated with spaceflight increase disease pathogens by activation of latent viruses?	3: Quantify latent herpes virus reactivation
Additional hypotheses as required.				

## III. Countermeasure Readiness Levels (CRL)

NASA's Biomedical Research and Countermeasures (BR&C) Program has developed a scale to allow NASA and the NSBRI to define, assess, and quantify the level of "countermeasure readiness." The use of this scale allows Program Managers to determine and describe how each funded research project fits into the countermeasure development "flow" and to monitor progress in countermeasure development. This section describes this scale and how it is used. **Each investigator must examine and understand the CRL scale and specify in the proposal the CRL that will result from the funding and conduct of their proposed research.** Figure 1 illustrates the CRL scale, which describes the level of scientific maturity of BR&C research from the fundamental studies that suggest potential countermeasures to studies that allow the systematic evaluation and validation of countermeasures ready for operational implementation.

Figure 1. Countermeasure Readiness Levels



Countermeasure development usually progresses through systematic research. Research flows through various levels of countermeasure readiness. Figure 2 represents this general progression. The boundaries between the types of activities are approximate. A potential countermeasure ready for validation in flight is one that has a thorough, successful history of ground-based, clinical, and/or flight analog testing. This NRA does not solicit CRL 7 and 8 research sponsored

by the Countermeasure Evaluation and Validation Project. Other NASA Research Announcements may be issued throughout the year to call for studies to evaluate potential countermeasures. To have NASA notify you by email in the future about its requests for research proposals, register at <a href="http://proposals.hq.nasa.gov/proposal.cfm">http://proposals.hq.nasa.gov/proposal.cfm</a>



Figure 2. Countermeasure Development Process

#### IV. Biomedical Data

Biomedical data are being collected in both the Longitudinal Study of Astronaut Health (LSAH) and the Life Sciences Data Archive (LSDA). These databases can be made available for research activities subject to scientific merit review, ethical issues related to the protection of subjects, and privacy issues. Identifiable human medical and research data is only available with the consent of the astronaut and/or research subject. Additional information can be obtained from Victor S. Schneider, M.D. (email: vschneider@nasa.gov or phone: 202-358-2204)

The LSAH is an electronic database of medical information collected over the active career and post career life of the astronauts. Data are also available on a comparison group matched to the astronauts at a 3:1 ratio by age, sex, and initial body mass index. The data recorded include annual and flight related medical evaluation and medical debriefs following space flights for astronauts and routine annual medical evaluations for the comparison group.

#### V. Review and Selection Process

This Appendix supersedes, modifies, or extends the requirements enumerated in Appendix E. All proposals must comply with the general requirements of the Announcement as described in both Appendices A and E. Appendices B and C contain specific requirements and explanations

for each opportunity above and beyond the NASA-specified requirements. Appendix E outlines the NASA-specified requirements for proposal submission and should be used for clarification and reference. Upon receipt, proposals will be reviewed for compliance with the requirements of this Announcement. This includes the following:

- 1. Submission of complete proposals specified in this Announcement. Proposals must be responsive to the areas of program element emphasis described in this Announcement and include a project description that is not more than 20 pages in length.
- 2. Submission, as specified in Appendices B and C to investigators, of appropriate Institutional Review Board (IRB) or Animal Care and Use Committee (ACUC) certification for all proposals using human or animal test subjects.
- 3. Submission of a budget within the guidelines specified in this Announcement and for a funding period not exceeding four years in duration.
- 4) Proposals that are revised versions of proposals previously submitted to NASA or the NSBRI must be clearly designated as such on the proposal cover page, and must contain an explanation of how the revised proposal has addressed criticisms from the previous NASA or NSBRI review. This explanation must be presented in a separate section of no more than two pages at the beginning of the project description, and is in addition to the 20 pages allowed for the project description. Related changes to the research plan should be highlighted in the body of the project description.
- 5) Submission of all other appropriate forms as required by this NASA Research Announcement (refer to Appendix F).

Note: Non-compliant proposals will be withdrawn from the review process and returned to the investigator without further review.

Compliant proposals submitted in response to this Announcement will undergo an intrinsic scientific or technical merit review. Only those proposals most highly rated in the merit review process will undergo the additional reviews for program relevance and cost. It should be noted that in order to achieve program balance, specific topics that are currently well represented in the BR&C Program portfolio will be de-emphasized. Investigators are encouraged to review summaries of the research currently funded in this program by accessing the Office of Biological and Physical Research Program Tasks and Bibliography (OBPR Task Book) at:

http://research.hq.nasa.gov/taskbook.cfm

#### **Scientific or Technical Merit Review**

A merit review of proposals submitted to this NRA will be conducted by panels of scientific or technical experts. A single set of discipline-specific panels, administered by NASA Peer Review Services, will evaluate all proposals submitted to this NRA. The number and diversity of experts required will be determined by the response to this NRA, and by the variety of disciplines represented in the proposals relevant to the research emphases described in Appendix B and C of this NRA. Merit review panels will *score proposals from 0-100*.

The scientific merit score assigned by each panel will not be affected by the proposed cost of the work, nor will it reflect the programmatic relevance of the proposed work to NASA. However, the panels will be encouraged to include comments concerning the proposal's budget and relevance to NASA or the NSBRI in the critique of each proposal, after it has been scored.

All of the following will be used in determining the merit score:

- **Significance:** Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or technology be advanced? What will be the effect of these studies on the concepts, methods, or products that drive this field? What is the likelihood that the proposed research will lead to new countermeasures or tests of the utility of countermeasures? Is there a significant societal or economic impact?
- **Approach:** Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Is the proposed approach likely to yield the desired results? Does the applicant acknowledge potential problem areas and consider alternative tactics? Are there strong interdisciplinary components?
- **Innovation:** Does the project employ novel concepts, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?
- **Investigator:** Are the scientists in the project, including collaborators, suitably trained for the proposed work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)? Is the evidence of the investigator's productivity satisfactory?
- **Environment:** Does the scientific environment in which the work will be performed contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

#### **Evaluation of Programmatic Relevance and Cost**

A **second review** of proposals will evaluate the programmatic relevance and cost of all proposed work. Evaluation of the cost of a proposed effort includes consideration of the realism and reasonableness of the proposed cost and the relationship of the proposed cost to available funds. Is the proposal responsive to the needs of NASA or the NSBRI *as expressed in this NRA*? Programmatic relevance will include an evaluation of how the proposed work may help achieve an appropriate balance of scientific and technical tasks required by critical research issues faced. Evaluation of programmatic relevance will vary according to the specific element of this NRA. NSBRI proposals will undergo a subsequent evaluation and scoring as to how well the proposal matches the NSBRI team's strategic plan. NSBRI proposals will be reviewed and prioritized by members of the NSBRI's Board of Scientific Counselors (BSC) on how well the proposal matches the NSBRI team's strategic plan. The results of the merit review and the BSC strategic

plan assessment will be forwarded to the NSBRI's External Advisory Council (EAC) for selection recommendations to the NSBRI Director. See Appendix C, Section V for more information on the NSBRI selection process.

#### **Development of a Selection Recommendation**

A selection recommendation will be developed based on the merit review, programmatic relevance, and cost, as described above. The most important element in the evaluation process is the merit review, which carries the highest weight in final evaluation and selection. The other factors are approximately equal in weight to each other. **Deficiencies in any one of these factors may prevent selection of a proposal.** The development of selection recommendations is the responsibility of NASA for the individual proposals submitted to the Biomedical Research and Countermeasures (BR&C) Program. The development of selection recommendations is the responsibility of the NSBRI for proposals submitted to the NSBRI elements of this NRA. Selections for funding of individual BR&C proposals will be made by the Director of the Bioastronautics Research Division, Office of Biological and Physical Research (OBPR), and selection of NSBRI proposals will be made by the NSBRI Director. Final selection will be coordinated between the Bioastronautics Research Division at NASA Headquarters and the NSBRI to ensure programmatic balance and elimination of duplicate efforts.

NASA and the NSBRI reserve the right to select and make an award covering only a portion of an investigator's project. The applicant will be given the opportunity to accept or decline such a partial award. If two or more proposals address similar problems and/or adopt similar approaches, NASA or the NSBRI may request that the investigators consolidate specific parts of their projects into a single project and work as a team. The selection review may also recommend changes in the way in which a specific proposal should be funded (i.e., as an individual investigator award or as a member of an NSBRI team). Acceptance of such a recommendation shall be at the discretion of the Principal Investigator. If a proposal submitted to NASA is found to be more appropriate to satisfy the NSBRI requirements, the Principal Investigator will be expected to become a full member of the appropriate NSBRI team. Any negotiations with a Principal Investigator will occur only after the peer review of proposals has been completed. Only grants will be awarded as a result of this NRA.

## VI. Program Reporting

It is expected that results from funded research will be published in peer-reviewed journals as the work is completed. Published papers must acknowledge NASA or NSBRI support. In addition, investigators whose proposals are selected must also provide annual reports on progress in achieving the goals of the research project.

**Final Report.** A final report is required that shall include a summary of completed research and a record of all scientific communications and peer-reviewed publications to date. This report must be submitted to the NASA Technical Monitor or to the NSBRI within 90 days after the end of the grant period.

Annual and final reports shall emphasize the relevance of research results to the CPR risks and questions defined in Table 1 in the original proposal. It should be noted that the final report shall incorporate the results and relevance to Table 1 for the entire duration of the research project.

## VII. Support of Education and Outreach

OBPR envisions that the selected individual investigator proposals will be structured and operated in a manner that supports the nation's educational initiatives and goals (including support of historically black colleges and universities and other minority universities), and in particular the need to promote scientific and technical education at all levels. OBPR envisions that the selected proposals will support the goals for public awareness and outreach to the general public (see Appendix E). The selected investigators are invited to participate in OBPR-funded educational programs.

Because the NSBRI has a unique team approach to experimental science, it has a separate education and public outreach component that adheres to these OBPR policies. For information on NSBRI's Education and Public Outreach Program, go to <a href="http://www.nsbri.org/Education/">http://www.nsbri.org/Education/</a>

### **OBPR Policy for Education (6-12) and Public Outreach**

The proposal represents an opportunity for NASA to enhance and broaden the public's understanding and appreciation of the value of OBPR research in the context of NASA's mission. Therefore, all principal investigators are strongly encouraged to promote general scientific literacy and public understanding of OBPR research through formal and/or informal education opportunities. If appropriate, proposals should include a clear and concise description of the education and outreach activities proposed. Examples include such items as involvement of students in the research activities, technology transfer plans, public information programs that will inform the general public of the benefits being gained from the research, and/or plans for incorporation of scientific results obtained into educational curricula consistent with educational standards. Where appropriate, the supported institution will be required to produce, in collaboration with NASA, a plan for communicating to the public the value and importance of their work.

Once NRA selections are made, the selected PI's will have an opportunity to request additional funding through an OBPR-sponsored pilot program to implement an education outreach program at the grades 6-12 level, at an amount not to exceed \$10,000 per year for the term of the grant. A request for proposal will accompany the selection notification letter. Proposals will be due within 60 days of selection notification and shall be limited to 4 pages. A review of these proposals by educational specialists will determine which proposals will be funded.

For more information, the OBPR Educational Outreach Vision, Mission, Goals and Operating Guidelines are provided in the Educational Outreach handbook. The handbook is available on the Internet at: <a href="http://spaceresearch.nasa.gov/research\_projects/nrahardware.html">http://spaceresearch.nasa.gov/research\_projects/nrahardware.html</a>. If you would like assistance in preparing outreach proposals, the National Space Grant College and Fellowship

Program is available to help. Visit their website at <a href="http://education.nasa.gov/spacegrant">http://education.nasa.gov/spacegrant</a> to identify the state-by-state listing of Space Grant Directors.

## VIII. Bibliography

- 1. **OBPR Program Tasks and Bibliography (Task Books)** for FY1995-2002 are available at http://research.hq.nasa.gov/taskbook.cfm
- 2. National Space Biomedical Research Institute Web site. <a href="http://www.nsbri.org/">http://www.nsbri.org/</a>
- 3. **Space Life Sciences Ground Facilities Information Package.** This document is available at http://research.hq.nasa.gov/code\_u/nra/current/NRA-03-OBPR-04/index.html
- 4. Guidebook for Proposers Responding to a NASA Research Announcement (NRA), 2003 edition: <a href="http://www.hq.nasa.gov/office/procurement/nraguidebook/">http://www.hq.nasa.gov/office/procurement/nraguidebook/</a>
- 5. Life Sciences research publications: <a href="http://spaceline.usuhs.mil/">http://spaceline.usuhs.mil/</a>
  Additional information may be obtained from the SPACELINE Project (phone: 301-295-2482; email: spaceline@usuhs.mil).
- 6. The Space Life Sciences Data Archive (LSDA) is an online database containing descriptions and results of completed NASA-sponsored flight experiments. Descriptions are included of experiments, missions, procedures, hardware, biospecimens collected, personnel, and documents. Biospecimens that are available for research purposes are described in detail. A limited number of experiments contain final reports and spreadsheet data suitable for downloading. Data from human subjects are unavailable online for reasons of privacy.

Internet address: <a href="http://lsda.jsc.nasa.gov/">http://lsda.jsc.nasa.gov/</a>

LSDA Help Desk: 281-483-7876 Email: lsda@semail.jsc.nasa.gov

- 7. Center for Advanced Studies in the Space Life Sciences contains a list of workshops and seminars sponsored by the Center. The proceedings and final reports of these workshops are also posted as they become available at <a href="http://www.mbl.edu/CASSLS/workshops.html">http://www.mbl.edu/CASSLS/workshops.html</a>
- 8. **Guidance for NASA Medical Board Procedures**. National Aeronautics and Space Administration, Medical Policy Board. Richard Williams, M.D., Chairperson. NASA Headquarters. This document is available at <a href="http://peerl.nasaprs.com/peer\_review/prog/mpbhand.pdf">http://peerl.nasaprs.com/peer\_review/prog/mpbhand.pdf</a>
- 9. **A Strategy for Research in Space Biology and Medicine in the New Century.**National Academy of Science. National Research Council Committee on Space Biology and Medicine. Mary J. Osborn, Committee Chairperson. 1998. Washington DC:
  National Academy Press. <a href="http://www.nas.edu/ssb/csbm1.html/">http://www.nas.edu/ssb/csbm1.html/</a>

- 10. **Space Physiology and Medicine**, **3<sup>rd</sup> ed**. A. Nicogossian, C. Huntoon, and S. Pool. (Eds.). 1994. Philadelphia, PA: Lea & Febiger.
- 11. **Task Force on Countermeasures.** This report incorporates the output of the Countermeasures Task Force, the Vestibular Countermeasures Task Group, and the Behavior and Performance Working Group into a unified document. This document is available at <a href="http://peerl.nasaprs.com/peer\_review/prog/countermeasures/countermeasures.html">http://peerl.nasaprs.com/peer\_review/prog/countermeasures/countermeasures.html</a>
- 12. **International Workshop on Cardiovascular Research in Space**. *Medicine and Science in Sports and Exercise*, Volume 28, Number 10 Supplement, 1996.
- 13. **Muscle Research in Space: International Workshop**. *International Journal of Sports Medicine*, Volume 18, Supplement 4, S257-S331, 1997.
- 14. **Space Neuroscience Research**. *Brain Research Reviews*, Volume 28, Numbers 1/2, Special Issue, 1998.
- 15. **International Workshop on Bone Research in Space**. *Bone, Official Journal of the International Bone and Mineral Society*, Volume 22, Number 5 (Supplement), 1999.
- 16. **Small Clinical Trials: Issues and Challenges.** Institute of Medicine, National Academy Press, Washington, DC. <a href="http://www.nap.edu/books/0309073332/html/">http://www.nap.edu/books/0309073332/html/</a>
- 17. **Sex and Gender: Exploring the Biological Contributions to Human Health**. *NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research*, 59 Fed. Reg. 14508 (1994).
- 18. **Grant and Cooperative Agreement Handbook.** Office of Procurement, National Aeronautics and Space Administration, Washington, D.C. 20546
- 19. **Safe Passage, Astronaut Care for Exploration.** Institute of Medicine, National Academy Press, 2101 Constitution Avenue NW, Washington DC 20418 (2001).
- 20. **NSBRI Team Strategic Plans:**

Bone Loss: <a href="http://www.nsbri.org/Research/Bone.html">http://www.nsbri.org/Research/Cardio.html</a>
Cardiovascular Alterations: <a href="http://www.nsbri.org/Research/Sleep.html">http://www.nsbri.org/Research/Sleep.html</a>
Human Performance Factors: <a href="http://www.nsbri.org/Research/Sleep.html">http://www.nsbri.org/Research/Sleep.html</a>
Immunology, Infection and Hematology: <a href="http://www.nsbri.org/Research/Immune.html">http://www.nsbri.org/Research/Immune.html</a>
Muscle Alterations and Atrophy: <a href="http://www.nsbri.org/Research/Muscle.html">http://www.nsbri.org/Research/Muscle.html</a>
Neurobehavioral and Psychosocial Factors: <a href="http://www.nsbri.org/Research/Psycho.html">http://www.nsbri.org/Research/Psycho.html</a>
Neurovestibular Adaptation: <a href="http://www.nsbri.org/Research/Neuro.html">http://www.nsbri.org/Research/Neuro.html</a>
Nutrition, Fitness and Rehabilitation: <a href="http://www.nsbri.org/Research/Nutrition.html">http://www.nsbri.org/Research/Nutrition.html</a>

Smart Medical Systems: <a href="http://www.nsbri.org/Research/Med\_Sys.html">http://www.nsbri.org/Research/Med\_Sys.html</a>
Technology Development: <a href="http://www.nsbri.org/Research/Tech.html">http://www.nsbri.org/Research/Tech.html</a>

21. Space and Life Sciences Directorate Web site: <a href="http://www.jsc.nasa.gov/sa/">http://www.jsc.nasa.gov/sa/</a>

## **NASA Research Announcement Ground-based Research Proposals**

## **Biomedical Research and Countermeasures Program**

## **Independent Investigator Research Projects**

NOTE 1: This Appendix should only be used for scientists interested in conducting an independent investigator research project. Scientists interested in team-based research should see Appendix C.

NOTE 2: Proposals for radiation research are not being solicited in this NRA. A separate NRA soliciting proposals for radiation research will be released later this year. To have NASA notify you by electronic mail in the future about its requests for research proposals, register at <a href="http://proposals.hq.nasa.gov/proposal.cfm">http://proposals.hq.nasa.gov/proposal.cfm</a>

## I. Introduction

The emphasis of this solicitation for ground-based research studies performed by individual investigators is to develop insights into physiologic changes that are likely to occur as a consequence of extended periods of flight. The BR&C Program supports basic, applied, and clinical research by individual investigators. Researchers may use hypogravity simulation models (e.g., bed rest, unilateral lower limb suspension, tail suspension, etc.) or hypergravity produced by centrifugation for their research studies. Experiments may use human subjects, animal models, or other appropriate models in the development of countermeasures.

## II. Emphases for Independent Investigator Research Projects

#### Research Emphases for FY 2003

This solicitation includes three elements, each focused on research that will lead to the development and ultimate use of countermeasures to the deleterious effects of space flight: 1) Physiology, 2) Behavior and Performance, and 3) Clinical Research in Support of Space Missions.

Mechanistic research is solicited that supports the development of ground-based biomedical countermeasures to the effects of space flight. A countermeasure to help astronauts is any means or procedural strategy that prevents or reduces the negative effects of space, or aids in the recovery upon return to Earth. It should be noted that the astronaut corps is diverse, comprised of men and women 30-60 years of age and of various ethnic backgrounds. Countermeasures should be robust enough to be efficacious across this population and be tailored for individual

specificity. Integrated approaches that study interactions between different physiological systems in the design and application of potential countermeasures are encouraged. Identifying the effects of experimental interventions on non-target systems as well as the targeted system is deemed to be of particular importance. Research to support the solution to operational and clinical problems is also sought.

It is expected that the average total annual (direct + indirect) cost of selected proposals will be \$250,000. The total annual cost of a single proposal should not exceed \$450,000.

### 1. Physiology

Proposals are requested for ground-based studies that will lead to a better understanding of the effects of space flight and exposure to microgravity on physiological function. Space physiology includes 1) fluid volume and cardiopulmonary, including cardiovascular alterations; 2) musculoskeletal, including bone loss and muscle alterations and atrophy; 3) neuroscience, including vestibular and sensorimotor function, and endocrine control; 4) immunology, infection, and hematology; 5) food, nutrition, and metabolism; and 6) integrative physiology; as well as 7) advanced technology development within the above elements. Studies that use integrated approaches are particularly encouraged. Proposals must represent questions and priorities enumerated in the Critical Path Roadmap at <a href="http://criticalpath.jsc.nasa.gov/">http://criticalpath.jsc.nasa.gov/</a>.

Contact: Bruce M. Hather, Ph.D./Bioastronautics Research Division

Telephone: 202-358-1796 Email: bhather@hq.nasa.gov

#### 2. Behavior and Performance

The Behavior and Performance element of the program addresses issues of 1) perception and cognition; 2) human physical performance; 3) personal, interpersonal, and group dynamics (coping, response to stress, etc.); 4) habitability; and 5) sleep and circadian rhythms. Studies should be directed towards understanding the effects of space flight on behavior and performance.

This element includes experiments designed to understand the mechanisms by which microgravity, confinement, cumulative sleep loss, mission design and events, spacecraft environment, noise and light, and sensory/cognitive or sensorimotor changes affect the behavior and performance of flight crews and ground-support crews. It also addresses psychosocial, gender, and cross-cultural aspects of human missions in space. Studies of relationships between individuals and individuals in groups are also addressed. Proposers may utilize existing databases and ground simulations in extreme and isolated analogs and test beds used to extrapolate to responses that might be expected in long-duration space flight. Behavior and performance research priorities for ground-based studies include the following:

### a. Psychological Research

Research is solicited that will lead to the development and validation of predictive tools for the assessment of psychological well-being, cognitive processing, mood, and emotion, especially as those are affected by multi-cultural and gender variables in long-duration space missions. Also of interest are hypothesis driven ground-based studies that would suggest and evaluate potential proactive techniques or strategies for reducing stress and improving well-being, mood, emotion, and cognitive processing in long-duration crews. Such techniques or strategies might include crew manipulation of environmental factors.

#### b. Psychiatric Issues

Research is required to understand how to detect and treat behavioral disorders that might occur in locations remote from usual health care facilities, e.g., during long-duration space flight.

Proposals must represent questions and priorities enumerated in the CPR at <a href="http://criticalpath.jsc.nasa.gov/">http://criticalpath.jsc.nasa.gov/</a>. For a broad, detailed listing of NASA Life Sciences Behavior and Performance research priorities, the Countermeasures Task Force Report on Behavior and Performance can be obtained online at

http://peer1.nasaprs.com/peer\_review/prog/countermeasures/countermeasures.html

Contact: Bette Siegel, Ph.D./Bioastronautics Research Division

Telephone: 202-358-2245 Email: bette.seigel@nasa.gov

# 3. Clinical Research in Support of Space Missions (Medicine in Extreme Environments)

The Clinical Research in Support of Space Missions element of the program focuses on research that will lead to development of medical knowledge and technologies required to maintain human health and performance in space and on return to Earth. Medical knowledge must be expanded so that the practice of Space Medicine in the microgravity environment can be evidence-based. Medical and surgical procedures, treatment, and imaging systems are required to diagnose and treat illnesses and injuries that may occur in space. The Clinical Research in Support of Space Missions element of the program solicits research required to improve or answer specific questions about in-flight diagnosis, therapy, and postflight rehabilitation.

#### a. Diagnosis

Ground-based research analogs for space flight research are required to complete the understanding of the patho-physiology, diagnosis, and therapeutic modalities required for implementation of an evidence-based practice of Space Medicine. Proposals for the development of non-invasive diagnostic tests and autonomous and semi-autonomous patient monitoring systems are requested. Research is also sought for the development of medical information systems that support the onboard medical provider.

#### b. Therapy

High priority will be given to research proposals to study the mechanisms of changes that could occur during space flight in the therapeutic effectiveness and adverse drug interactions of medications for common illnesses. Proposals are sought for research to enhance surgical capabilities in space. High priority will be given to proposals that investigate the application of fiber optic-based and minimally invasive surgical techniques.

Proposals are sought in medical education focused on the development and maintenance of medical capabilities for both physicians and non-physician crew medical officers. Priority will be given to those research proposals that develop and test new training paradigms. Priority will be given to proposals that address the development of space flight treatment capabilities for acute medical and surgical emergencies such as wounds, lacerations, and burns; toxic exposures; decompression illness; and dental, ophthalmologic, urologic, gastrointestinal, and gynecologic emergencies.

**Risk Evaluation** c.

High priority will be given to research proposals that will evaluate whether the presence of a patent foramen ovale increases the medical risk (incidence and morbidity) related to decompression sickness.

#### d. Rehabilitation

Proposals are sought for research to develop more effective rehabilitation techniques for deconditioned space travelers on their return to Earth.

#### Pharmaceuticals and Blood Replacement Solutions e.

Proposals are sought for ground-based research that emphasizes efficacy and route of administration of pharmaceuticals, intravenous fluids, and blood replacement substances that are stored for extended periods of time and would be required for clinical care of patients in extreme environments (e.g., radiation resistant, storage at ambient temperature, small volume, etc.).

Proposals must represent questions and priorities enumerated in the Critical Path Roadmap at Investigators must complete Form F in Appendix F for http://criticalpath.jsc.nasa.gov/. consideration of their proposal.

Contact: Victor S. Schneider, M.D./Bioastronautics Research Division

> Telephone: 202-358-2204 Email: vschneider@nasa.gov

## III. Application Procedures for Independent Investigator Research Projects

Except where specifically stated otherwise in this NRA, applicants must prepare proposals in accordance with the "Instructions for Responding to NASA Research Announcements," which is part of the NASA Federal Acquisition Regulations (FAR) Supplement (NFS), Part 1852.235-72 (Appendix E).

## **Instructions for Notice of Intent and Proposal Submission**

## A. SYS-EYFUS Registration for All Applicants

SYS-EYFUS is an electronic system used by NASA Headquarters to manage research solicitation activity, plan for the receipt of research proposals, track the receipt and peer evaluation of these proposals, and manage funded research (grants, cooperative agreements, etc.) sponsored by NASA's Office of Equal Opportunity (Code E), Office of Earth Science (Code Y), Office of Human Resources & Education Division (Code F), Office of Biological and Physical Research (Code U), Office of Space Science (Code S), and the Office of Space Flight (Code M). SYS-EYFUS also supports the funding and administration of awards pursuant to selection of these research opportunities.

# The SYS-EYFUS Help Desk is available at 202-479-9376. Help desk hours are from 8 a.m. to 6 p.m. Eastern time.

All investigators planning to submit a proposal to this solicitation are requested to register online with SYS-EYFUS. Comprehensive help, instructions, and contact information are provided online. SYS-EYFUS can be accessed at <a href="http://proposals.hq.nasa.gov/">http://proposals.hq.nasa.gov/</a>.

If you have previously registered with SYS-EYFUS, you are requested to verify and update your user information. If you have forgotten your user ID or password, select the "Forgot Your Password" option and type in your first and last name to search our database. The system will send an automatic email message with your username and password to the email address listed in our database.

## B. Instructions for Preparing a Notice of Intent

All investigators planning to submit a proposal in response to this solicitation are requested to submit a **non-binding** notice of intent (NOI) to propose by the due date identified in the Summary and Supplemental Information Section of this NRA via the Web at the following address:

#### http://proposals.hq.nasa.gov/proposal.cfm

1) Login to SYS-EYFUS at the URL listed above and select "New Notice of Intent."

- 2) The Division Specific Opportunities screen will appear. In the selection window, highlight **Bioastronautics Research Division** and click on "Continue."
- 3) The List of Existing Opportunities screen will appear. In the selection window, highlight **03-OBPR-04** and then click on "Continue."
- 4) This will bring you to the Notice of Intent Submission Form. All fields are required.
  - a. Please select from **only** the following three options: For the proposal type field on this form, new / no prior support means that the investigator has not received NASA funding from 1999 through 2002, new/prior support means that the investigator has received NASA funding between 1999 and 2002, and revised means that the proposal is a revised version of a proposal submitted to NASA and reviewed from 1999 through 2002, but not funded. A proposal previously submitted but not funded, should be identified as being "revised" even if the original Principal Investigator has changed.
- 5) Click on "Submit NOI Page."
- 6) The Team Member Page screen will appear, where you can add or remove team members. Select continue if there are no other team members. To add a team member, highlight the role option on the selection list, type in first and last name and click on search. When the resulting set appears, choose the appropriate radio button and click on ADD to add the person to the NOI. After you are done, click on "Continue." IMPORTANT: If the team member is not listed in our database, please have them add themselves as a new user to the system. You may then add them to your team member list.
- 7) After continuing from the Team Members Page, your NOI will be displayed. Click on "Resubmit NOI Page" to complete your NOI submission.
- 8) You may edit and resubmit your NOI at any time before the submission deadline of May 15, 2003. Once you submit an NOI, it cannot be deleted, only edited. For title, team member, or any other changes, please edit your existing NOI and resubmit changes to avoid duplicate records.

# C. Instructions for Preparing and Electronically Submitting a Proposal Cover Page

All investigators planning to submit a proposal in response to this solicitation must electronically submit proposal cover page information online and provide a hardcopy of the cover page attached to each proposal copy by the due date indicated in the Summary and Supplemental Information Section of this NRA. The proposal cover page can be submitted and printed at

http://proposals.hq.nasa.gov/proposal.cfm

- 1) Login to SYS-EYFUS at the URL listed above.
- 2) To submit a New Proposal Cover Page, click the "New Proposal Cover Page" option on the SYS-EYFUS Options screen, and the New Proposals Cover Page screen will appear.
- 3) If you previously submitted an NOI in response to this solicitation, choose to carry over the existing NOI. This option will populate the cover page fields with the NOI information. Edit the information as necessary, click "Continue," and proceed to #8 below.
- 4) If you did not previously submit an NOI, click on New Proposal Cover Page option, and the Division Specific Opportunities screen will appear.
- 5) In the selection window, highlight **Bioastronautics Research Division** and click on "Continue."
- 6) The List of Existing Opportunities screen will appear. In the selection window, highlight **03-OBPR-04** and then click on "Continue."
- 7) This will bring you to the Proposal Cover Page Submission Form. Fill in all the fields. All fields are required.
  - a. Please select from **only** the following three options: For the proposal type field on this form, new / no prior support means that the investigator has not received NASA funding from 1999 through 2002, new / prior support means that the investigator has received NASA funding between 1999 through 2002, and revised means that the proposal is a revised version of a proposal submitted to NASA and reviewed from 1999 through 2002, but not funded. A proposal previously submitted but not funded should be identified as being "revised" even if the original Principal Investigator has changed.
  - b. Indicate the status of IRB/IACUC for your proposal. If IRB or IACUC review is unavoidably delayed beyond the submission of the application, enter "Pending" on the Proposal Cover Page, and be advised that the certification must be received within 90 days after the due date for which the application is submitted.
  - c. Provide your TIN and CAGE numbers. Every U.S. institution that submits a proposal to a U.S. agency must provide their permanently-assigned Taxpayer Identification Number (TIN) and must register with the Department of Defense Central Contractor Registration (CCR) database for a permanently-assigned Commercial and Government Entity (CAGE) number. Reference the 2003 NRA Proposers Guidebook <a href="http://www.hq.nasa.gov/office/procurement/nraguidebook/">http://www.hq.nasa.gov/office/procurement/nraguidebook/</a> for additional information. If you are unsure of your institution's TIN number, please contact your institution's Office of Sponsored Research to obtain the your

institution's Taxpayer Identification Number (TIN) or Employer Identification Number (EIN).

Click on "Continue."

8) The Team Member Page screen will appear, where you can add or remove team members. Every proposal must specify the critically important personnel who are expected to play a significant role in the execution of the proposed effort and their institution of employment. Categories of personnel to be included as Team Members are described in Appendix B, Section III, Part D(5) and in Section 1.4.2 in the 2003 NRA Proposers Guidebook

(http://www.hq.nasa.gov/office/procurement/nraguidebook/)

You must include your authorizing official as a team member. When you complete and print the proposal cover page, you will see signature blocks both for yourself and your authorizing official. You are required to submit one original signed (by both you and your authorizing official) cover page with your proposal hardcopies.

**IMPORTANT:** If the team member is not listed in our database, please have them add themselves as a new user to the system. You may then add them to your team member list.

Select "Continue" if there are no other team members. To add a team member, highlight the role option on the selection list, type in first and last name and click on search. When the resulting set appears, choose the appropriate radio button and click on ADD to add the person to the proposal. After you are done, click on "Continue."

- 9) After continuing from the Team Member Page, the Proposal Options Page appears.
- 10) Please fill out the budget form by clicking on the "Budget" button, filling in project costs, and clicking "Continue." This will bring you to the Proposal Budget Review Page. Click "Continue" if the information is correct.
- 11) After verifying your budget information, you will be returned to the Proposal Options Page. Click the "Show/Print" button.
- 12) For detailed budget information, you must use Forms C and D, provided at <a href="http://research.hq.nasa.gov/code\_u/nra/current/NRA-03-OBPR-04/nra\_forms2.rtf">http://research.hq.nasa.gov/code\_u/nra/current/NRA-03-OBPR-04/nra\_forms2.rtf</a> Sample copies of Forms C and D are also available in Appendix F.

Form D must be filled out for each year of grant support requested.

These forms cannot be electronically submitted. Fill out the forms and attach them to your proposal.

13) At the page entitled Proposal Information Item List, click "Continue" to preview your Proposal Cover Page. Print the cover page from your Internet browser once you have reviewed the information. The cover page must be signed by both the Principal Investigator and the authorizing official and attached to the front of your proposal before submission of hard copies to NASA.

By signing and submitting the proposal identified on the cover sheet, the Authorizing Official of the proposing institution (or the individual investigator if there is no proposing institution): 1) certifies that the statements made in the proposal are true and complete to the best of his/her knowledge; 2) agrees to accept the obligations to comply with NASA Award terms and conditions if an award is made as a result of this proposal; 3) provides certification to the following that are reproduced in their entirety in Appendix D of this NRA: (i) Certification Regarding Debarment, Suspension and Other Responsibility matters, (ii) Certification Regarding Lobbying, and (iii) Certification of Compliance with the NASA Regulations Pursuant to Nondiscrimination in Federally Assisted Programs.

12) You may edit and resubmit your proposal cover page at any time before the submission deadline as indicated in the Summary and Supplemental Information Section of this NRA. Please note that once you submit a proposal cover page, it can only be edited, not deleted. For title, team member, budget or any other changes, please edit your existing proposal cover page and resubmit changes to avoid duplicate records.

## D. Instructions for Preparation and Delivery of Proposals

<u>All</u> proposals submitted must include the completed cover page form as described in this Appendix. The name of the Principal Investigator should appear in the upper right hand corner of each page of the proposal except on the cover page form, where special places are provided for this information. Note that the proposal <u>must</u> specify the period of performance for the work described; periods of performance may be for any duration up to the maximum duration identified in the Announcement section of this NRA but should be suitable for the project proposed.

Please use the proposal submission checklist template form (Appendix F, Form A), located at <a href="http://research.hq.nasa.gov/code\_u/nra/current/NRA-03-OBPR-04/nra\_forms2.rtf">http://research.hq.nasa.gov/code\_u/nra/current/NRA-03-OBPR-04/nra\_forms2.rtf</a>, to assist you in assembling your proposal.

#### The proposal must include the following material, in this order:

(1) Proposal Cover Page: Solicited Proposal Application, including certification of compliance with U.S. code (if applicable). One signed original required. Please see "Instructions for Preparing and Electronically Submitting a Proposal Cover Page" (Appendix B, Section III, Part C) for instructions on how to complete the proposal cover page information.

- (2) Transmittal Letter or Prefatory Material, if any (see Appendix E, "Instructions for Responding to NASA Research Announcements," for details).
- (3) Proposal Title Page, with Notice of Restriction on Use and Disclosure of Proposal Information, if any (see Appendix E, "Instructions for Responding to NASA Research Announcements," for details).

## (4) Project Description

The length of the Project Description section of the proposal <u>cannot exceed 20 pages</u> using regular (12 point) type. Text must be printed on one side only and should have the following margins: left = 1.5"; Right, top, bottom = 1.0". Referenced figures must be included in the 20 pages of the Project Description. The Bibliography section is not considered part of the 20-page project description. Proposals that exceed the 20-page limit for the project description (22-page limit for revised proposals; see below) will not be reviewed. The proposal should contain sufficient detail to enable reviewers to make informed judgments about the overall merit of the proposed research and about the probability that the investigators will be able to accomplish their stated objectives with current resources and the resources requested. In addition, the proposal should clearly indicate the relationship between the proposed work and the research emphases defined in this Announcement. Reviewers are not required to consider information presented as appendices or to view and/or consider Web links in their evaluation of the proposal.

<u>New applications</u> where the investigator has received NASA funding in related fields from 1999 through 2002: Results and evidence of progress of the associated NASA supported research must be presented as part of the project description. See "Instructions for Responding to NASA Research Announcements" for details.

Revised applications (revisions of 1999 through 2002 submissions) must be so designated on the proposal cover page and explained in the project description. This explanation should be presented in a separate section of **no more than two pages at the beginning of the project description**, and is in addition to the 20 pages allowed for the project description. Related changes to the research plan should be highlighted in the body of the project description. Changes within the proposal may be highlighted by appropriate bracketing, indenting, or changing of typography. Clearly present any work done since the prior version was submitted. **Revised applications that do not address the criticisms in the previous review will be considered non-responsive and will be returned without review.** See "Instructions for Responding to NASA Research Announcements" for additional information.

#### (5) Management Approach

Each proposal <u>must</u> specify a single Principal Investigator who is responsible for carrying out the proposed project and coordinating the work of other personnel involved in the project. In proposals that designate several senior professionals as

key participants in the research project, the management approach section should define the roles and responsibilities of each participant and note the proportion of each individual's time to be devoted to the proposed research activity. The proposal must clearly and unambiguously state whether these key personnel have reviewed the proposal and endorsed their participation.

Investigators are strongly encouraged to identify only the most critically important personnel (Team Members) to aid in the execution of their proposals. Should such positions be necessary, Co-Investigators (Co-Is) may be identified who are critical for the successful completion of research through the contribution of unique expertise and/or capabilities, and who serve under the direction of the PI, regardless of whether or not they receive compensation under the award. Most NRAs require a Co-I to have a well-defined role in the research that is defined in the Management section of the proposal. Evidence of a Co-I's commitment to participate is often requested through a brief letter to be included with the proposal.

Co-Principal Investigators (Co-PIs) are not permitted with the sole exception when a non-U.S. Co-Investigator is proposed. This exception is described in the third subcategory below.

There are three subcategories of Co-Is that a proposal may identify, as appropriate:

- A Co-I may be designated as the <u>Science PI</u> for those cases where the proposing institution does not permit that individual to formally serve as the PI as defined above. In such a case, the Science PI will be understood by NASA to be in charge of the scientific direction of the proposed work, although the formally designated PI is still held responsible for the overall direction of the effort and use of funds.
- A Co-I may be designated as an <u>Institutional PI</u> when their institution is making a <u>major</u> contribution to a proposal submitted by a PI from another institution.
- A Co-I from a <u>non-U.S.</u> institution may be designated as a <u>Co-Principal Investigator</u> (Co-PI) should such a designation serve required administrative purposes in that Co-I's institution and/or for the procurement of funding by that Co-I from their sponsoring funding authority.

Additional Team Member category positions are often included in proposals as defined as follows:

A <u>Postdoctoral Associate</u> holds a Ph.D. or equivalent degree and is identified as a major participant in the execution of the proposed research. Such personnel may be identified by name or only by function in those cases where their recruitment depends on the successful selection of the proposal.

<u>Other Professional</u> is a description appropriate for personnel who support a proposal in a critical albeit intermittent manner, such as a consulting staff scientist or a key Project Engineer and/or Manager, who is not identified as a Co-I or Postdoctoral Associate.

A <u>Graduate Student</u> included in a proposal is working for a post-graduate degree and will support the proposed research under direction of the PI. Such a student may be identified by name or only by function in case their recruitment depends on the successful selection of the proposal.

A <u>Collaborator</u> is an <u>unfunded</u> position included in a proposal, whose participation is less critical than a Co-I, but who is committed to provide a specific contribution to the proposal.

(6) Personnel/Biographical Sketches (Appendix F, Form B)

The biographical sketch for each investigator must not exceed two pages. If the list of qualifications and publications exceeds two pages, select the most pertinent information (see "Instructions for Responding to NASA Research Announcements" for details). You must use the biographical sketch form (Form B, Appendix F) located at:

http://research.hq.nasa.gov/code\_u/nra/current/NRA-03-OBPR-04/nra\_forms2.rtf

This form cannot be electronically submitted. Fill out Form B for each investigator and attach it to your proposal.

- (7) Facilities and Equipment (see Appendix E, "Instructions for Responding to NASA Research Announcements," for details).
- (8) Special Matters (specific information on animal or human subjects protocol approval required, if applicable).

For proposals employing human subjects and/or animals, assurance of compliance with human subjects and/or animal care and use provisions is required on the Proposal Cover Page. In addition, the application must include a statement from the applicant institution certifying that the proposed work will meet all Federal and local human subjects requirements and/or animal care and use requirements.

Policies for the protection of human subjects in NASA sponsored research projects are described in NASA Management Instruction (NMI) 7100.8B (*Protection of Human Research Subjects*). Animal use and care requirements are described in the NASA Code of Federal Regulations (CFR) 1232 (*Care and Use of Animals in the Conduct of NASA Activities*). Both documents are available from the Office of Biological and Physical Research, Code UB, NASA Headquarters, Washington, DC 20546.

#### Additional Requirements for Research Employing Human Subjects

A letter signed by the Chair of the Institutional Review Board (IRB) <u>identifying the proposal submitted to NASA by title</u> and certifying approval of proposed human subjects protocols and procedures should be included with each copy of the proposal. <u>IRB certifications for other research proposals or grants cannot be substituted</u> (even if they employ the same protocols and procedures).

If IRB certification is pending on the proposal due date, select "pending" from the IRB/IACUC section menu on the Proposal Cover Page, and include with each copy of the proposal <u>a letter signed by the IRB Chair identifying the proposal by title</u> and indicating the status of the IRB review process at the time of submission. <u>IRB certification must be received no later than 90 days after the proposal due date.</u> An application lacking the required IRB certification 90 days after the proposal due date will be considered incomplete and may be returned to the applicant without review.

With regard to research involving human subjects, NASA and the NSBRI have adopted the National Institutes of Health (NIH) policy. Women and members of minority groups and their subpopulations must be included in NASA-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided showing that inclusion of these groups is inappropriate with respect to the health of the subjects or the purpose of the research.

NASA will require current IRB certification prior to each year's award.

#### Additional Requirements for Research Employing Animals

## Specific information describing and justifying the use of animal subjects must be included in the proposal.

A letter signed by the Chair of the Institutional Animal Care and Use Committee (IACUC) identifying the proposal submitted to NASA by title and certifying approval of the proposed animal research protocols and procedures should be included with each copy of the proposal. The institution's Public Health Service Animal Welfare Assurance Number must be included on the IACUC certification and entered in the IRB/IACUC section of the Proposal Cover Page. <u>IACUC certifications for other research proposals or grants cannot be substituted</u> (even if they employ the same protocols and procedures).

If IACUC certification is pending on the proposal due date, select "pending" from the IRB/IACUC selection menu on the Proposal Cover Page, and include with each copy of the proposal <u>a letter signed by the IACUC Chair identifying the proposal by title</u> and indicating the status of the IACUC review process at the time of submission. IACUC certification must be received no later than 90 days after the proposal due

<u>date.</u> An application lacking the required IACUC certification 90 days after the proposal due date will be considered incomplete and may be returned to the applicant without review.

NASA will require current IACUC certification prior to each year's award.

(9) Detailed Budget and Supporting Budgetary Information (Appendix F, Forms C and D).

For detailed budget information, you must use Forms C and D, provided at <a href="http://research.hq.nasa.gov/code\_u/nra/current/NRA-03-OBPR-04/nra\_forms2.rtf">http://research.hq.nasa.gov/code\_u/nra/current/NRA-03-OBPR-04/nra\_forms2.rtf</a>

Form D must be filled out for each year of grant support requested.

These forms cannot be electronically submitted. Fill out the forms and attach them to your proposal.

NASA is expected to be operating on the basis of full cost accounting as soon as possible, including all Civil Service salaries with overhead. In the interim period, proposals should use the accounting method authorized at their institutions at the time proposals are due and for the entire proposed period of performance. Funds to support the Resident Research Assistant (RRA) Postdoctoral Program costs (e.g., stipend, travel, computer time, supplies, etc.) are to be budgeted within the NASA intramural Principal Investigator budget.

If travel is planned, the proposal budget should include appropriate travel funds for visits to NASA field centers (as appropriate) and presentation of findings at professional society meetings.

In this solicitation, the terms "cost" and "budget" are used synonymously. Sufficient proposal cost detail and supporting information are required; funding amounts proposed with no explanation (e.g., Equipment: \$1,000, or Labor: \$6,000) may cause delays in evaluation and award. Generally, costs will be evaluated for realism, reasonableness, allowability, and allocation. The budgetary forms define the desired detail, but each category should be explained. Offerors should exercise prudent judgment in determining what to include in the proposal, as the amount of detail necessarily varies with the complexity of the proposal.

The following examples indicate the suggested method of preparing a cost breakdown:

#### Direct Labor

Labor costs should be segregated by titles or disciplines with estimated hours and rates for each. Estimates should include a basis of estimate, such as currently paid rates or outstanding offers to prospective employees. This format allows the

Government to assess cost reasonableness by various means including comparison to similar skills at other organizations.

#### Other Direct Costs

Please detail, explain, and substantiate other significant cost categories as described below:

- <u>Subcontracts</u>: Describe the work to be contracted, estimated amount, recipient (if known), and the reason for subcontracting.
- <u>Consultants</u>: Identify consultants to be used, why they are necessary, the time they will spend on the project, and the rates of pay.
- Equipment: List separately. Explain the need for items costing more than \$5,000. Describe basis for estimated cost. General-purpose equipment is not allowable as a direct cost unless specifically approved by the NASA Grant Officer. Any equipment purchase requested as a direct charge must include the equipment description, how it will be used in the conduct of the basic research proposed, and why it cannot be purchased with indirect funds.
- <u>Supplies</u>: Provide general categories of needed supplies, the method of acquisition, and estimated cost.
- <u>Travel</u>: Describe the purpose of the proposed travel in relation to the grant, and provide the basis of estimate, including information on destination and number of travelers (if known).
- Other: Enter the total of direct costs not covered by a) through e). Attach an itemized list explaining the need for each item and the basis for the estimate.

#### **Indirect Costs**

Indirect costs should be explained to an extent that will allow the Government to understand the basis for the estimate. Examples of prior year historical rates, current variances from those rates, or an explanation of other basis of estimates should be included. Where costs are based on allocation percentages or dollar rates, an explanation of rate and application base relationships should be given. For example, the base to which the General and Administrative (G&A) rate is applied could be explained as: application base equals total costs before G&A less subcontracts.

All awards made as a result of this NRA maybe funded as grants or contracts. However, while proposals submitted by "for profit" organizations are allowed, they cannot include a "fee."

- (10) Other Support: You must complete Form E for specific sources of other support for the principal investigator and each Co-Investigator (not consultants). Form E is available at <a href="http://research.hq.nasa.gov/code\_u/nra/current/NRA-03-OBPR-04/nra\_forms2.rtf">http://research.hq.nasa.gov/code\_u/nra/current/NRA-03-OBPR-04/nra\_forms2.rtf</a>
- (11) Appendices, if any (reviewers are not required to consider information presented in appendices).

(12) One (1) signed original and twenty (20) copies of the proposal cover page and the proposals must be received by **5:00 p.m.**, **July 15, 2003**, at the following address:

NASA Peer Review Services SUBJECT: 03-OBPR-04 BR&C Ground-based Research Proposal 500 E Street SW, Suite 200 Washington, DC 20024 202-479-9030

## **IV.** Compliance Matrix

The following information is specific to this NRA and **supersedes** the information contained in paragraphs (i) and (j) of "Instructions for Responding to NASA Research Announcements."

All proposals must comply with the general requirements of the Announcement as described in both Appendices A, B and Appendix E "Instructions for Responding to NASA Research Announcements." Appendices A and B contain specific requirements and explanations for each section of the proposal above and beyond the NASA-specified requirements. Appendix E, "Instructions for Responding to NASA Research Announcements," outlines the NASA-specified requirements for proposal submission and should be used for clarification and reference. Upon receipt, proposals will be reviewed for compliance with the requirements of this Announcement. This includes the following:

- 1. Submission of complete proposals specified in this Announcement. Proposals must be responsive to the areas of program element emphasis described in this Announcement and include a project description that is not more than 20 pages in length.
- 2. Submission of appropriate Institutional Review Board (IRB) or Animal Care and Use Committee (ACUC) certification for all proposals using human or animal test subjects.
- 3. Submission of a budget that is within the guidelines specified in this Announcement and is for a funding period not exceeding that described in the Announcement.
- 4. Proposals that are revised versions of proposals previously submitted to NASA must be clearly designated as such on the proposal cover page and must contain an explanation of how the revised proposal has addressed criticisms from previous NASA review. This explanation should be presented in a separate section of no more than two pages at the beginning of the project description and is in addition to the 20 pages allowed for the project description. Related changes to the research plan should be highlighted in the body of the project description.
- 5. Submission of all other appropriate information as required by this NASA Research Announcement (refer to Appendices A and B).

Note: At NASA's discretion, non-compliant proposals may be withdrawn from the review process and returned to the investigator without further review.

Compliant proposals submitted in response to this Announcement will undergo an intrinsic scientific or technical merit review. Only those proposals most highly rated in the merit review process will undergo additional reviews for program relevance and cost.

## V. Eligibility

All categories of institutions are eligible to submit proposals in response to this NRA, but only approved proposals from U.S. institutions will be selected for funding. Principal Investigators may collaborate with universities, Federal Government laboratories, the private sector, and state and local government laboratories. In all such arrangements, the applying entity is expected to be responsible for administering the project according to the management approach presented in the proposal.

The applying entity must have in place a documented base of ongoing high quality research in science and technology or in those areas of science and engineering clearly relevant to the specific programmatic objectives and research emphases indicated in this Announcement. Present or prior support by NASA of research or training in any institution or for any investigator is neither a prerequisite to submission of a proposal nor a competing factor in the selection process.

## VI. Guidelines for International Participation

Guidelines for International Participation are detailed in paragraph (l) of Appendix E of this Announcement.

Export Control Guidelines Applicable to Foreign Proposals and Proposals Including Foreign Participation. Foreign proposals and proposals including foreign participation must include a section discussing compliance with U.S. export laws and regulations, e.g., 22 CFR Parts 120-130 and 15 CFR Parts 730-774, as applicable to the circumstances surrounding the particular foreign participation. The discussion must describe in detail the proposed foreign participation and is to include, but not be limited to, whether or not the foreign participation may require the prospective investigator to obtain the prior approval of the Department of State or the Department of Commerce via a technical assistance agreement or an export license, or whether a license exemption/exception may apply. If prior approvals via licenses are necessary, discuss whether the license has been applied for or if not, the projected timing of the application and any implications for the schedule. Information regarding U.S. export regulations is available at http://www.pmdtc.org/and http://www.bxa.doc.gov/.Investigators are advised that under U.S. law and regulations, spacecraft and their specifically designed, modified, or configured systems, components, and parts are generally considered "Defense Articles" on the United States Munitions List and are subject to the provisions of the International Traffic in Arms Regulations (ITAR), 22 CFR Parts 120-130.

### **NASA Research Announcement Ground-based Research Proposals**

### **Biomedical Research and Countermeasures Program**

# Research Projects for a Research Team of the National Space Biomedical Research Institute

NOTE 1: The National Space Biomedical Research Institute (NSBRI) is soliciting integrative, cross-disciplinary proposals dealing with the effects of space radiation on a variety of aspects of human functioning in space. The Institute will not, however, be accepting proposals for the Radiation Effects Team. Proposals that synergistically bridge multiple disciplines for the purpose of modeling the effects of microgravity on the human body to aid in the development and testing of countermeasures, or to develop technologies that enable research in one or more NSBRI research areas are strongly encouraged. Applications that incorporate innovative bioinformatics approaches to acquisition and assessment of biomedical data are also invited.

NOTE 2: The overall focus for NSBRI proposals must be the definition and feasibility of specific practical countermeasures (CRLs 3-7).

NOTE 3: Only investigators who are applying to join one of the NSBRI research teams listed in Section I should use this appendix for the preparation of their application. Scientists interested in submitting proposals for independent investigator research projects should refer to Appendix B.

### I. Introduction

The NSBRI is a private, non-profit organization competitively selected by NASA. The mission of the Institute is to use an integrated research team approach to advance biomedical research with the goal of ensuring safe and productive long-term human exploration of space. The NSBRI invites ground-based research applications to join an existing team in one of 10 research areas:

- 1. *Bone Loss* Addressing bone loss and weakening during space flight, and the inherent fracture risks.
- 2. Cardiovascular Alterations Addressing the in-flight occurrence of cardiac dysrhythmias and post-flight impairment of the cardiovascular response to orthostatic and exercise stress.

- 3. *Human Performance Factors, Sleep, and Chronobiology* Investigating maintenance of high cognitive performance and vigilance despite environmental stress and sleep disturbances.
- 4. *Immunology, Infection, and Hematology* Addressing immune system impairment and altered susceptibility to infection, increased allergic responsiveness, decreased blood volume, and post-flight anemia.
- 5. *Muscle Alterations and Atrophy* Focusing on the loss of skeletal muscle mass, strength, and endurance that accompanies space flight.
- 6. *Neurobehavioral and Psychosocial Factors* Investigating methods and tools that can be utilized to enable crews to cope with stress, isolation, and compatibility.
- 7. *Neurovestibular Adaptation* Addressing the problems of space motion sickness and disorientation during flight and the post-flight problems of balance and gaze disorders.
- 8. *Nutrition, Physical Fitness, and Rehabilitation* Developing methods to maintain health and fitness before, during, and after space flights.
- 9. *Smart Medical Systems* Developing new methods of non-invasive medical monitoring, diagnosis, and therapy for use on space missions.
- 10. *Technology Development* Developing instrumentation and other technological products that will enhance the research of the other teams and benefit people on Earth.

Each of the ten research teams consists of a set of coordinated and complementary projects focused on a common theme. Team management and coordination is the responsibility of the **Team Leader**. A single Team Leader, assisted by an Associate Team Leader, heads each research team. Team Leaders play a pivotal role in guiding the Institute's research program and in the ultimate success of the Institute. Their expertise and "hands-on" approach to research management add value across projects and across teams. The Team Leader is guided by the Critical Path Roadmap (CPR), which is the cornerstone for developing the team's integrated strategic research plan, the key to accomplishing the Institute's mission.

Team Leader positions for all ten teams will be competed in parallel with this Announcement. See the Call for Candidates for more information on how to apply for these leadership positions at <a href="http://www.nsbri.org/Announcements/callforcandidates.html">http://www.nsbri.org/Announcements/callforcandidates.html</a>

Research proposals will be accepted from all categories of organizations, public and private, and for-profit and non-profit, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the Federal Government. The mechanism of support shall be an NSBRI sub-agreement with funds provided by NASA through a cooperative agreement (Cooperative Agreement NCC 9-58) with NASA's Lyndon B. Johnson Space Center. Progress of the funded research will be reviewed annually. *Potential foreign applicants should note that, normally, the country of origin, not the NSBRI, must fund applications from non-U.S. organizations. Potential foreign applicants should coordinate their application with both the NSBRI and the appropriate funding agency in their own country.* 

### II. Background

The NSBRI is responsible for the development of countermeasures against the deleterious effects of long-duration space flight and applied space biomedical research directed toward this specific

goal. Its mission is to lead a national effort in integrated, critical path space biomedical research that supports NASA's Bioastronautics Strategy by focusing on the enabling of long-term human presence in, development of, and exploration of space. This is accomplished by:

- designing and testing effective countermeasures to address the biological and environmental impediments to long-term human space flight;
- defining the molecular, cellular, organ-level, and integrated responses and mechanistic relationships that ultimately determine these impediments, where such activity is essential for the development of novel countermeasures;
- establishing biomedical support technologies to maximize human performance in space, reducing biomedical hazards to an acceptable level, and delivering quality medical care;
- transferring and disseminating the biomedical advances in knowledge and technology to the general benefit of mankind; and
- ensuring open involvement of a diverse scientific community, industry, and the public at large in the Institute's activities and fostering a robust partnership with NASA, particularly through NASA's Lyndon B. Johnson Space Center.

#### **Institute Infrastructure**

The NSBRI is governed by a consortium of twelve institutions: Baylor College of Medicine; Brookhaven National Laboratory; Harvard Medical School; The Johns Hopkins University School of Medicine and the Applied Physics Laboratory; Massachusetts Institute of Technology; Morehouse School of Medicine; Mount Sinai School of Medicine; Rice University; Texas A&M University; the University of Arkansas for Medical Sciences; the University of Pennsylvania Health System; and the University of Washington. The Institute's Headquarters are located in Houston, at Baylor College of Medicine.

This is an open solicitation. Consortium membership is not a requirement for research **program participation.** The management plan for the Institute is based on the model used by the National Institutes of Health. An independent Board of Scientific Counselors (BSC) is responsible for assuring excellence in the Institute's research program through independent external peer review. An External Advisory Council (EAC) is responsible for advising Institute management and the Board of Directors (comprised of, but not limited to, representatives from the senior management of each of the 12 NSBRI Consortium member institutions) concerning program strategy, tactical implementation, and effectiveness. The NSBRI also has a User Panel of former and current astronauts and flight surgeons responsible for assuring that the research program is focused squarely on astronaut health and safety. An Industry Forum of representatives from the space and biomedically-related industries advises and assists the NSBRI concerning Earth- and space-based applications for Institute research. In addition to its research program, the NSBRI has developed a vital education and outreach program that takes advantage of the Institute's core research activities. The Institute coordinates its research activities with NASA through a joint NASA/NSBRI Steering Committee.

### **Call for Candidates – Team Leaders**

As described in the NSBRI Policy on Team Leadership

(http://www.nsbri.org/Announcements/callforcandidates.html), Team Leaders are selected by the NSBRI Director with the approval of the NSBRI Board of Directors for a term that is identical with the term of their NSBRI-funded research project. The NSBRI is soliciting applications for team leaders on a competitive basis. Current Team Leaders may reapply for the next term. Prospective Team Leaders must prepare and submit in response to this solicitation, as Principal Investigator, a proposal that achieves a merit score in the competitive range as a prerequisite for being considered for a Team Leadership position. All applications for Team Leader positions will be considered new applications. No special consideration will be given to current Team Leaders who reapply. A separate application process will be used to select Team Leaders. Do not make any reference to your interest in becoming a Team Leader in your NSBRI proposal application.

For more information about applying for a Team Leadership position, go to the Call for Candidates at <a href="http://www.nsbri.org/Announcements/callforcandidates.html">http://www.nsbri.org/Announcements/callforcandidates.html</a>.

### III. Specific Research Focus and Opportunity

#### **General Information**

To carry out the NSBRI's primary mission of identifying, designing and developing effective countermeasures to address the biological and environmental impediments to human space flight, the NSBRI focuses its research program on the primary needs of long-duration missions (e.g., several months on the International Space Station, exploration class missions, etc.). These missions pose the greatest challenge to present and future space travelers, and meeting these challenges with appropriate countermeasures lies at the core of the NSBRI's responsibility.

Potential physiological changes that may occur during prolonged space flight include, among others, significant loss of muscle and bone mass, decreased dietary intake of nutrients, profound metabolic and endocrine alterations, important changes in cardiovascular function, and deleterious effects on sensorimotor performance. By addressing long-term missions, increased crew safety, health, and performance will be realized for shorter-duration space flights.

NSBRI research is conducted in partnership with NASA using an **integrated team approach**. The teams focus on high priority biomedical research problems and investigators work together, within and between teams, to address complex risks that often require interdisciplinary expertise and resources. The value added in the integrated team approach leads to more effective outcome-driven research than what is obtainable by a single project alone.

The NSBRI has an essential enabling role for NASA: providing capabilities for countermeasures development research. The Institute engages scientists, engineers, and clinicians and utilizes the resources of institutions to form a biomedical research community. Countermeasures research conducted by the NSBRI integrates a biomedical research community with the engineering and operational expertise of NASA to effectively manage health risks for long-duration human space flight.

The NSBRI's research program contains studies that, for the most part, range from CRL 3 through 7. Each proposer must examine and understand the CRL scale and specify in the proposal the CRL that will result from the funding and conduct of the proposed research. For further information, refer to Appendix A.

For more information on the NSBRI, see <a href="http://www.nsbri.org/">http://www.nsbri.org/</a>.

### **NSBRI Team Specific Research Focus and Opportunity**

Proposals submitted to the NSBRI in response to this NRA must address one of the ten research areas discussed below. Proposals that impact more than one area should be directed to only one primary research area, although a secondary research area may be designated if the proposal has significant overlap with that area. Studies that use integrated methods are particularly encouraged.

It is recommended that investigators carefully review the Team Strategic Plan of the team(s) relevant to a proposal. These plans are referenced in the following subsections, which are meant to guide the investigator to the key problems and issues that are central to each research area. In all cases, proposals must represent questions and be relevant to priorities enumerated in the CPR at <a href="http://criticalpath.jsc.nasa.gov/">http://criticalpath.jsc.nasa.gov/</a>.

Proposals in radiation, modeling, space medicine, and technology that are relevant to countermeasure development within the scope of the NSBRI mission are invited but must address one of the 10 research areas discussed below. The NSBRI seeks innovative projects of varying duration (up to four years) and scope that will produce clear deliverables in the CRL 3-7 range. Proposers are encouraged to define clear milestones and to collaborate with NASA scientists, engineers, flight surgeons, and astronauts, as appropriate, to maximize the likelihood of success and impact of their proposed research.

### 1. NSBRI Bone Loss Team

The Bone Loss Team studies the mechanisms involved in bone loss related to microgravity, the development of countermeasures to prevent bone loss, and methods for evaluating the rate of loss and the impact on fracture risk. Team information and the Team Strategic Plan for countermeasures research and development, including research goals and priorities, are located at <a href="http://www.nsbri.org/Research/Bone.html">http://www.nsbri.org/Research/Bone.html</a>.

Proposals are sought whose research addresses, but is not limited to, the following areas and questions:

- What pharmacological, nutritional, or mechanical treatments, or combinations thereof, effectively diminish the loss of bone mass in weightless or non-weight bearing conditions that simulate microgravity? Investigation of this question may require chronic bed rest studies.
- Which factors (genetic, baseline values, fitness, etc.) determine the wide variation in inter-individual rates and site-specific patterns of bone loss?
- Which radiological or imaging methods best permit geometric or structural analysis of patterns and rates of bone loss in humans subjected to microgravity?

- Is there a means of accelerating the recovery of bone following exposure to weightlessness? Does the delayed return of bone mass to pre-flight levels increase injury risk during rehabilitation? If so, how can bone recovery be accelerated?
- What is the nature and incidence rate of soft connective tissue injury and related symptoms during and after prolonged space flight?
- Can one quantify the incidence or extent of injury to intervertebral discs during weightlessness or upon return to normal gravity?
- Which procedures will protect against soft tissue injury in-flight and hasten repair of damaged soft tissues?
- Can alterations in the timing and consolidation of fracture callus that forms during disuse/microgravity be normalized, and with what pharmacological or mechanical interventions?
- What modalities are practical for space flight applications that might accelerate fracture healing?
- Can fracture risk be accurately predicted from novel modeling techniques developed from available bone loss data collected on astronauts/cosmonauts?
- The development of novel nutritional and pharmacological countermeasures to reduce renal stone formation.

Proposals must represent questions and priorities enumerated in the CPR at <a href="http://criticalpath.jsc.nasa.gov/">http://criticalpath.jsc.nasa.gov/</a>. Investigators must complete Form F in Appendix F for consideration of the proposal. Form F can be found in the downloadable documents section of the on-line proposal submission system. After completion, Form F should be uploaded as an Appendix in the on-line proposal.

### 2. NSBRI Cardiovascular Alterations Team

The Cardiovascular Alterations Team is focused on understanding the mechanisms of and identifying effective solutions to conditions wherein astronauts may experience heart rhythm disturbances, cardiac atrophy, and a drop in blood pressure, causing faintness, reduced exercise capacity, and decreased function following landing. Team information and the Team Strategic Plan for countermeasures research and development, including research goals and priorities, are located at <a href="http://www.nsbri.org/Research/Cardio.html">http://www.nsbri.org/Research/Cardio.html</a>.

Proposals are sought whose research addresses, but is not limited to, the following areas and questions:

- Countermeasures to reduce impaired cardiovascular responses to orthostatic stress.
- Occurrence of serious cardiac dysrhythmias and methods to predict and prevent such events.
- Cardiac atrophy and remodeling.
- Techniques to address the manifestation of previously asymptomatic cardiovascular disease that may present during space missions.
- Impaired cardiovascular response to exercise stress.
- Development of new cardiovascular technologies for space flight and Earth based applications.
- Individual susceptibility to the adverse effects of space flight on the cardiovascular system.
- Strategies for short-term and long-term cardiovascular rehabilitation following space flight.

Proposals must represent questions and priorities enumerated in the CPR at <a href="http://criticalpath.jsc.nasa.gov/">http://criticalpath.jsc.nasa.gov/</a>. Investigators must complete Form F in Appendix F for consideration of the proposal. Form F can be found in the downloadable documents section of the on-line proposal submission system. After completion, Form F should be uploaded as an Appendix in the on-line proposal.

### 3. NSBRI Human Performance Factors, Sleep, and Chronobiology Team

The Human Performance Factors, Sleep, and Chronobiology Team is developing ways to reduce human mistakes and optimize mental and physical performance during long-duration space flight. The loss of 24-hour day/light cycle, weightlessness, a confined environment, and work demands make sleep difficult in space. Cumulative sleep loss increases the risk of accidents and possible mission failure. Team information and the Team Strategic Plan for countermeasures research and development, including research goals and priorities, are located at <a href="http://www.nsbri.org/Research/Sleep.html">http://www.nsbri.org/Research/Sleep.html</a>.

Proposals are sought whose research addresses, but is not limited to, the following areas and questions:

- Which photic, behavioral, environmental, pharmacological, nutritional, and/or exercise countermeasures will help crew members reduce disturbances of circadian rhythmicity, sleep disturbances, or homeostatic sleep drive, thereby reducing the associated performance deficits?
- How can performance during prolonged space flight be optimized by manipulating the neurobiological processes underlying sleep and/or circadian rhythmicity?
- What are the most sensitive and specific methods for monitoring the ongoing status of sleep, sleep homeostasis, circadian regulation, and individual light exposure, performance capability, metabolic functions, and physical health during extended duration space flight?
- What are the best optimization techniques for using mathematical models of sleep homeostasis and circadian regulation to specify and schedule countermeasure strategies?
- What measures of sleep, sleep disorders, or circadian function predict individual neurobehavioral performance, adaptation, metabolic function, physical health, or countermeasure efficacy?
- What are the effects of space flight on the pharmacokinetics, efficacy, side effects, and interactions (drug-drug, drug-sleep, drug-circadian) of therapeutic agents designed to improve sleep, circadian regulation, cognitive performance, and physical health?
- What technological and procedural advances can minimize the probability of error by astronauts whose abilities may be impaired by fatigue or circadian disruption?
- How can advances in computer-aided decision making, on-board training, or smart check lists be applied to offset cognitive deficits?
- How can recent advances in the neurobiology of sleep and/or circadian rhythms (e.g., orexin/hypocretin system, circadian photoreception, output pathways for regulation of sleep or circadian rhythms, peripheral oscillators) be used to develop countermeasures to facilitate adaptation to the space environment and thereby maintain optimal neurobehavioral performance during an exploration-class space mission?
- How do countermeasures intended for other physiologic systems (e.g., exercise, activity schedules) interact with sleep, circadian organization, and waking function in long

duration space flight? How might the timing of such countermeasure administration be used to improve sleep, circadian organization, waking performance, or physical health?

Proposals must represent questions and priorities enumerated in the CPR at <a href="http://criticalpath.jsc.nasa.gov/">http://criticalpath.jsc.nasa.gov/</a>. Investigators must complete Form F in Appendix F for consideration of the proposal. Form F can be found in the downloadable documents section of the on-line proposal submission system. After completion, Form F should be uploaded as an Appendix in the on-line proposal.

### 4. NSBRI Immunology, Infection, and Hematology Team

The Immunology, Infection, and Hematology Team is examining the effects that extended space flight might have on virus reactivation and a weakened immune system. Radiation damage to the bone marrow stem cell raises concern of space flight-related anemia and other blood cell deficiencies following a mission. Team information and the Team Strategic Plan for countermeasures research and development, including research goals and priorities, are located at <a href="http://www.nsbri.org/Research/Immune.html">http://www.nsbri.org/Research/Immune.html</a>.

Proposals are sought whose research addresses, but is not limited to, the following areas and questions:

- Effect of space environmental conditions on long-term risks of viral-induced malignancies.
- Countermeasures to address radiation effects on host control of infection: mucosal vs. systemic immunity.
- Effects of microgravity and/or radiation on virulence of microbes and on the host: microorganism homeostasis.
- Assessment of space station vs. deep space radiation effects on bone marrow.
- Pleuripotent stem cells and hematopoietic progenitor cells: iron, silicon.
- Effects of space radiation on T-cell function.
- Mechanisms of transmission of microbial agents in space flight conditions.
- Role of defensins in wound-healing in space.
- Development of monitoring systems for microorganisms and virus reactivation.
- Stem cell reconstitution using an irradiated mouse model.
- Mechanisms to resist infections and malignancies in space: nutritional supplements, hormones, antibodies, pharmaceuticals, and vaccines.
- Use of gene inserts to develop resistance to radiation-induced pathogens.

Proposals must represent questions and priorities enumerated in the CPR at <a href="http://criticalpath.jsc.nasa.gov/">http://criticalpath.jsc.nasa.gov/</a>. Investigators must complete Form F in Appendix F for consideration of the proposal. Form F can be found in the downloadable documents section of the on-line proposal submission system. After completion, Form F should be uploaded as an Appendix in the on-line proposal.

### 5. NSBRI Muscle Alterations and Atrophy Team

The Muscle Alterations and Atrophy Team's objective is to develop methods to prevent or reduce muscle loss on space missions. While astronauts exercise in space, current exercise regiments alone are not sufficient to prevent potentially deleterious changes that occur in skeletal

muscle during space flight. The Team works to identify effective physical countermeasures (i.e., exercise prescriptions) and to combine this strategy with other countermeasures, such as improved nutrition and pharmacological interventions. Team information and the Team Strategic Plan for countermeasures research and development, including research goals and priorities, are located at <a href="http://www.nsbri.org/Research/Muscle.html">http://www.nsbri.org/Research/Muscle.html</a>.

Proposals are sought whose research addresses, but is not limited to, the following areas and questions:

- Effects of resistance training as a countermeasure to muscle alterations and atrophy in simulated microgravity (e.g. altered loading states).
- Are there synergistic effects when various activity paradigms are carried out simultaneously with other countermeasures, such as nutritional modification and/or pharmacological intervention and other strategies, such as antioxidants and vitamin supplements?
- Is it necessary to maintain or regain muscle mass in order to maintain muscle strength and power generating capacity?
- Are there practical programs predicated on activity paradigms that can maintain the normal phenotypes typically seen in the muscles of humans and animals?
- How do altered loading states affect the sensory motor processes that affect posture, balance, and the performance of locomotor tasks of varying intensity and complexity?
- What are the stress/strain reactions that impact force production, and do muscle atrophy and injury processes affect these properties?
- Are atrophying skeletal muscle, the myotendinous junctions, tendons, and ligaments more prone to injury and are the mechanisms of recovery from injury altered?
- How does artificial gravity (e.g., gravity-equivalent acceleration and variable-G forces) affect the structure and function of human skeletal muscle in normal and atrophying skeletal muscle?
- Are there systems other than skeletal muscle that are impacted by artificial gravity?
- Can artificial gravity approaches interact with other paradigms impacting high stress levels on the musculoskeletal system?

Proposals must represent questions and priorities enumerated in the CPR at <a href="http://criticalpath.jsc.nasa.gov/">http://criticalpath.jsc.nasa.gov/</a>. Investigators must complete Form F in Appendix F for consideration of the proposal. Form F can be found in the downloadable documents section of the on-line proposal submission system. After completion, Form F should be uploaded as an Appendix in the on-line proposal.

### 6. NSBRI Neurobehavioral and Psychosocial Factors Team

The Neurobehavioral and Psychosocial Factors Team is concerned with methods crews use to deal with stress, isolation, confinement, and the challenges of long duration space missions. In addition to identifying neurobehavioral and psychosocial risks to crew health, safety, and productivity, team objectives include developing methods to monitor brain functions and behavior and countermeasures to enhance performance, motivation, and quality of life. Leadership style, crew composition, organization, and communication are also being investigated to optimize crew effectiveness and mission success. Team information and the Team Strategic Plan for countermeasures research and development, including research goals and priorities, are located at <a href="http://www.nsbri.org/Research/Psycho.html">http://www.nsbri.org/Research/Psycho.html</a>.

Proposals are sought whose research addresses, but is not limited to, the following areas and questions:

- What are the effects of culture, gender, personality, leadership, and training on performance, stress, and health in isolated groups in confined environments and ground-based, analog environments for space flight?
- What are the major influences on interpersonal actions, communications, and problem solving in small isolated groups and what techniques can be developed to optimize group dynamics and performance?
- How can affective, neurobehavioral, and neurocognitive dysfunction be objectively detected in remote locations?
- What objective, unobtrusive methods and approaches will permit detection of stress, declining cognitive, emotional, and social functions, and changes in operationally relevant performance capabilities during space flight?
- What are the effects of space radiation on cognitive and other brain functions, and what countermeasure strategies should be developed to minimize the potential harmful central nervous system effects of radiation exposure?
- What neurobiological processes of stress and arousal are the optimal targets for behavioral and pharmacological interventions?
- What behavioral and pharmacological interventions are optimal in space flight?
- What are the effects of long-term exposure to the major factors in the space environment on emotions (including emotional reactivity, stress neurobiology and responses, modulation of mood, and vulnerability to affective disorders), cognition and performance (including processes of sensation and perception, learning, vigilance, problem solving, decision making, and motor skills), and behavioral health?
- What are the behavioral strategies, scheduling and timeline approaches, and habitability design elements that can maintain or enhance crew performance and prevent the development of hostility within flight crews and between crews and ground-support personnel during long-duration space flight?
- How can mathematical models of human interaction and the temporal dynamics of human behavior help predict responses in space flight?

Proposals must represent questions and priorities enumerated in the CPR at <a href="http://criticalpath.jsc.nasa.gov/">http://criticalpath.jsc.nasa.gov/</a>. Investigators must complete Form F in Appendix F for consideration of the proposal. Form F can be found in the downloadable documents section of the on-line proposal submission system. After completion, Form F should be uploaded as an Appendix in the on-line proposal.

### 7. NSBRI Neurovestibular Adaptation Team

The Neurovestibular Adaptation Team is developing potential preflight and in-flight countermeasures to allow crew members to adjust more rapidly to gravitational changes that can result in disorientation, motion sickness and a loss of sense of direction. These problems have an impact on space motion sickness, landing and post-flight adaptation. Team information and the Team Strategic Plan for countermeasures research and development, including research goals and priorities, are located at <a href="http://www.nsbri.org/Research/Neuro.html">http://www.nsbri.org/Research/Neuro.html</a>.

Proposals are sought whose research addresses, but is not limited to, the following areas and questions:

- What causes the profound impairments of posture, gaze, visual acuity, ataxia, and locomotion stability in astronauts, and what countermeasures minimize these impairments to reduce re-entry and landing vertigo, acute space motion sickness, post-flight imbalance, and in-flight spatial orientation?
- Are some crew members more susceptible to re-entry and landing vertigo than others and does repeated microgravity experience confer significant immunity?
- Can new, safe, and effective anti-motion sickness drugs be developed which specifically target emetic centers or the vestibular-emetic linkage, act rapidly, and do not impair cognition or performance?
- Can improved anti-motion sickness delivery systems and dose and side effect monitoring systems be developed, and what are the best ground-based methods for assessing the effectiveness and side effects of drug countermeasures and for evaluating microgravity pharmacokinetics?
- Are there non-pharmacologic techniques (e.g., parabolic flight preadaptation, head movement restriction) which could significantly reduce the incidence of acute space motion sickness, or which could mitigate the impact of emesis on EVA life support systems?
- What is the effect of cardiovascular, muscle, and skeletal rehabilitation therapies on neurovestibular recovery, and the converse?
- Can preflight or inflight training, balance exercises, sensory aids, prostheses, and assessment techniques improve postlanding postural and locomotor control and functional task performance?
- What spacecraft architectures and interior visual cues minimize disorientation?
- What are the effects of artificial gravity on human orientation and eye, head, and limb movements, and what are the pros and cons of various types of artificial gravity as countermeasures against the effects of microgravity on neurovestibular function?
- Does long-term exposure to microgravity or partial gravity, radiation, or environmental toxins cause functionally important, irreversible (pathophysiological) changes in central or peripheral vestibular and sensorimotor function, development, or plasticity, or cause acceleration of the normal aging process?
- Does microgravity-altered calcium homeostasis impact otoconial formation, and if there are important effects, what countermeasures are appropriate?

Proposals must represent questions and priorities enumerated in the CPR at <a href="http://criticalpath.jsc.nasa.gov/">http://criticalpath.jsc.nasa.gov/</a>. Investigators must complete Form F in Appendix F for consideration of the proposal. Form F can be found in the downloadable documents section of the on-line proposal submission system. After completion, Form F should be uploaded as an Appendix in the on-line proposal.

### 8. NSBRI Nutrition, Physical Fitness and Rehabilitation Team

The Nutrition, Physical Fitness, and Rehabilitation Team is addressing the quality and quantity of dietary intake, exercise, and rehabilitation to reduce or eliminate muscle atrophy and bone loss, and to improve altered cardiovascular function. The Team is also examining countermeasures to reduce the biomedical risks of radiation, circadian alterations, and other factors associated with long duration human space missions. Team information and the Team Strategic Plan for countermeasures research and development, including research goals and

priorities, are located at <a href="http://www.nsbri.org/Research/Nutrition.html">http://www.nsbri.org/Research/Nutrition.html</a>.

Proposals are sought whose research addresses, but is not limited to, the following areas and questions:

- Understanding mechanisms and designing effective nutritional countermeasures to the deficiencies in thirst and nutrient intake, with relevance to changes that may occur during human space flight.
- Establishing ground-based clinical measurements of biochemical alterations that may indicate depression of food intake.
- Developing monitoring methods for assessment of food intake and physical activity that are relevant to the space environment.
- Nutrition and/or physical fitness countermeasures to high priority problems, with emphasis on radiation-enhanced carcinogenesis, depression of cognitive function, bone loss, and loss of muscle mass and function.
- Studies that assess the effectiveness of aerobic and resistive exercise countermeasures, with endpoint parameters that quantify the cardiovascular response, bone metabolism, body composition, and skeletal muscle metabolism and function.
- Assessment of exercise countermeasures that include strict dietary control and contain measures of energy balance.
- Development of accurate methods to assess body composition changes relevant to human space flight.

Proposals must represent questions and priorities enumerated in the CPR at <a href="http://criticalpath.jsc.nasa.gov/">http://criticalpath.jsc.nasa.gov/</a>. Investigators must complete Form F in Appendix F for consideration of the proposal. Form F can be found in the downloadable documents section of the on-line proposal submission system. After completion, Form F should be uploaded as an Appendix in the on-line proposal.

### 9. NSBRI Smart Medical Systems Team

The Smart Medical Systems Team is developing and applying new technologies for physiological and medical monitoring and clinical care that integrate novel hardware, intelligent algorithms and models, and new therapeutic approaches applicable for remote health care in the space environment and on Earth. The Team works closely with the Technology Development Team and the Space Medicine group at Johnson Space Center. Team information and the Team Strategic Plan for countermeasures research and development, including research goals and priorities, are located at <a href="http://www.nsbri.org/Research/Med\_Sys.html">http://www.nsbri.org/Research/Med\_Sys.html</a>.

Proposals are sought whose research addresses, but is not limited to, the following areas:

- Novel sensor systems for remote physiological monitoring and medical diagnosis.
- Novel diagnostic and therapeutic hardware modalities to reduce risk and problems associated with trauma and acute medical conditions that might occur in the space environment.
- Innovative imaging strategies with automated, intelligent diagnostic interpretation capabilities.
- Methods to reduce risk of and manage toxic exposure in a space environment.

- Methods to better understand and reduce risk of altered pharmacodynamics, adverse drug reactions, and drug interactions.
- Decision support systems and knowledge bases for diagnosis and treatment that interface humans and machines, and enhance clinical care and medical training for crew medical officers and flight surgeons.

Proposals must represent questions and priorities enumerated in the CPR at <a href="http://criticalpath.jsc.nasa.gov/">http://criticalpath.jsc.nasa.gov/</a>. Investigators must complete Form F in Appendix F for consideration of the proposal. Form F can be found in the downloadable documents section of the on-line proposal submission system. After completion, Form F should be uploaded as an Appendix in the on-line proposal.

### 10. NSBRI Technology Development Team

The Technology Development Team develops new devices and systems to improve research techniques for the other teams, and adds value to the enabling scientific and medical technologies already supported by the other teams and by NASA. Projects focus on designing lightweight, compact research tools and on developing simple, minimally-invasive and non-invasive methods of gathering health-related data that are relevant to space missions and have Earth-based applications. Team information and the Team Strategic Plan for countermeasures research and development, including research goals and priorities, are located at <a href="http://www.nsbri.org/Research/Tech.html">http://www.nsbri.org/Research/Tech.html</a>.

Proposals are sought whose research addresses, but is not limited to, the following areas:

- Development of multi-purpose instruments or devices to monitor physiological measures (e.g., vital signs, core body temperature, eye motion, body fluid chemistry, etc.) using sensors and sensor systems that are easy to use, non-invasive (or minimally invasive), comfortable to wear, unobtrusive, and non-interfering with task performance.
- Innovative technologies applicable to the space environment to detect and identify pathogens (including bacteria, fungi, and viruses) in air, water samples, food, and human specimens, utilizing small sample volumes, fast read-out, and automated methods.
- Development of automated approaches to carrying out biochemical assays (especially inflight) with minimal operator intervention.
- Development of novel devices to collect blood and other bodily fluids with minimum crew disturbance and discomfort.
- Advanced cabin communications and information management systems, including wireless and infrared optical systems, to facilitate the collection and analysis of important biological information without tethering or otherwise hampering astronaut activities.
- Low mass, compact diagnostic and therapeutic tools and equipment that use minimum spacecraft resources and augment the efforts of the NSBRI Smart Medical Systems Team and NASA Space Medicine to enrich the in-flight clinical status evaluation of crews.

Proposals must represent questions and priorities enumerated in the CPR at <a href="http://criticalpath.jsc.nasa.gov/">http://criticalpath.jsc.nasa.gov/</a>. Investigators must complete Form F in Appendix F for consideration of the proposal. Form F can be found in the downloadable documents section of the on-line proposal submission system. After completion, Form F should be uploaded as an Appendix in the on-line proposal.

# IV. Application Procedures for the Opportunity to Participate on a National Space Biomedical Research Institute Team

Proposals to join an NSBRI research team must comply with the requirements of this research opportunity as described in this appendix (Appendix C). Appendix D outlines general NASA-specified requirements for proposal submission and should be used only for clarification of matters not specifically discussed here. Appendix C supersedes, modifies, or extends the requirements enumerated in Appendix D.

#### **General Instructions**

Proposals to join one of the NSBRI's ten research teams must be submitted through NSBRI's Internet-based Electronic Proposal Submission System (EPSS). Applications for NSBRI Team Leadership will be handled separately from this solicitation. Please go to the Call for Candidates at <a href="http://www.nsbri.org/Announcements/callforcandidates.html">http://www.nsbri.org/Announcements/callforcandidates.html</a> for information on applying for Team Leadership positions.

The EPSS has been designed to enable investigators to collaborate on the development of a proposal, to retain complete privacy throughout the proposal development process, and to allow fast and accurate proposal submission. If a proposal is selected for funding, the electronic proposal information will serve as an active record file, enabling simplified investigator information changes, annual report submission, and NASA Task Book submission.

The Notice of Intent to propose is prepared and electronically submitted through EPSS. To assure that the notice of intent is submitted by **May 15**, **2003**, go to the Web site <a href="http://myportal.nsbri.org/">http://myportal.nsbri.org/</a> and register to obtain a personal account on the system. After entering contact information, investigators will receive a username and password for entry into EPSS and can enter the limited information required for a notice of intent. After this, the above Web address will serve as the entry point for proposal development and modification. All information entered, with the exception of that required for the notice of intent, will remain private until electronic submission is completed.

Proposal information requested in EPSS closely follows the information requested by NIH grant application form PHS 398. This information includes Basic Personal and Institutional Information, Project Description, Performance Sites, Key Personnel, Investigator Budgets with Justifications, Other Support, Biographical Sketches, Laboratory Resources, and Research Plan.

A proposal overview screen will guide applicants through the process of completing the required proposal information. EPSS offers a collaborative work environment for the Principal Investigator and Co-Investigators to view and submit various portions of the proposal. For example, the Principal Investigator can enter or upload <u>all</u> information for the proposal. Co-Investigators can view most of the proposal information but are permitted to enter only their <u>specific</u> personal information and their assigned project and budgetary information. All investigators can allow an administrative support person to act on their behalf, to assist in the entry of proposal information; however, electronic submission can only be performed by the Principal Investigator. EPSS will contain an Investigator Profile section, containing biographical sketches and other information, for each investigator registered in the system. This information

can be used by authorized proposing investigators, eliminating the duplicate entry of such information.

Electronic proposals and applications must be submitted before 5:00 p.m. EST, Tuesday, July 15, 2003. After submission using EPSS, the Principal Investigator must mail the printed proposal cover page that is generated by the system, with the appropriate institutional approvals, to the following address within **one week** of the submission deadline:

NSBRI, *Attn: NRA 03-OBPR-04* One Baylor Plaza, NA-425 Houston, TX 77030-3498 713-798-7412

Please direct any questions concerning this application procedure to the NSBRI by calling 713-798-7412, by faxing your questions to 713-798-7413, or by sending your inquiry to contact\_us@www.nsbri.org. The technical requirements to operate EPSS are Internet Explorer 4.0+ or Netscape 4.03+ for Windows, Macintosh, or Unix. EPSS is best viewed using Internet Explorer 6.0.

<u>Eligibility</u> – All categories of institutions are eligible to submit proposals in response to this NRA, but, in most cases, only approved proposals from U.S. institutions will be selected for funding. Principal Investigators may collaborate with universities, Federal Government laboratories, the private sector, and state and local government laboratories. In all such arrangements, the applying entity is expected to be responsible for administering the project according to the management approach presented in the proposal.

The applying entity must have in place a documented base of ongoing high quality research in science and technology or in those areas of science and engineering clearly relevant to the specific programmatic objectives and research emphases indicated in this Announcement. Present or prior support by NASA or the NSBRI of research or training in any institution or for any investigator is neither a prerequisite to submission of a proposal nor a competing factor in the selection process.

<u>Notice of Intent</u> – To facilitate planning for the review process, investigators are requested to submit a notice of intent to propose by using EPSS and following the online instructions. This non-binding notification should be submitted electronically by May 15, 2003.

<u>Budgetary Matters</u> – Budgets are to be prepared according to the instructions provided online through EPSS. It is expected that the <u>average</u> annual total (direct + indirect) cost of selected proposals will be approximately \$250,000. In general, the annual total cost of a single proposal should not exceed \$450,000. **NSBRI** awards require a cost-sharing arrangement with the institution consisting of an augmentation of at least 10% in addition to the total NSBRI award. This contribution should not be identified in the submitted project budget but will be requested at the time the institutional award is made.

<u>Special Matters</u> – (specific information on animal or human subjects protocol approval required, if applicable).

For proposals employing human subjects and/or animals, assurance of compliance with human subjects and/or animal care and use provisions is required on the Proposal Cover Page. In addition, the application must include a statement from the applicant institution certifying that the proposed work will meet all Federal and local human subjects requirements and/or animal care and use requirements.

Policies for the protection of human subjects in NASA sponsored research projects are described in NASA Management Instruction (NMI) 7100.8B (*Protection of Human Research Subjects*). Animal use and care requirements are described in the NASA Code of Federal Regulations (CFR) 1232 (*Care and Use of Animals in the Conduct of NASA Activities*). Both documents are available from the Office of Biological and Physical Research, Code UB, NASA Headquarters, Washington, DC 20546.

### Additional Requirements for Research Employing Human Subjects

A letter signed by the Chair of the Institutional Review Board (IRB) <u>identifying the proposal submitted to NASA by title</u> and certifying approval of proposed human subjects protocols and procedures should be included in the appendix of the proposal. <u>IRB certifications for other research proposals or grants cannot be substituted</u> (even if they employ the same protocols and procedures).

If IRB certification is pending on the proposal due date, select "pending" from the IRB/IACUC section menu on the Proposal Cover Page, and include in the appendix of the proposal a letter signed by the IRB Chair identifying the proposal by title and indicating the status of the IRB review process at the time of submission. IRB certification must be received no later than 90 days after the proposal due date. An application lacking the required IRB certification 90 days after the proposal due date will be considered incomplete and may be returned to the applicant without review.

With regard to research involving human subjects, NASA and the NSBRI have adopted the National Institutes of Health (NIH) policy. Women and members of minority groups and their subpopulations must be included in NASA-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided showing that inclusion of these groups is inappropriate with respect to the health of the subjects or the purpose of the research.

NSBRI will require current IRB certification prior to each year's award.

### Additional Requirements for Research Employing Animals

Specific information describing and justifying the use of animal subjects must be included in the proposal.

A letter signed by the Chair of the Institutional Animal Care and Use Committee (IACUC) <u>identifying the proposal submitted to NBSRI by title</u> and certifying approval of the proposed animal research protocols and procedures should be included in the appendix of the proposal. The institution's Public Health Service Animal Welfare Assurance Number must be included on the IACUC certification and entered in the IRB/IACUC section of the Proposal Cover Page. <u>IACUC certifications for other research proposals or grants cannot be substituted</u> (even if they employ the same protocols and procedures).

If IACUC certification is pending on the proposal due date, select "pending" from the IRB/IACUC selection menu on the Proposal Cover Page, and include in the appendix of the proposal a letter signed by the IACUC Chair identifying the proposal by title and indicating the status of the IACUC review process at the time of submission. IACUC certification must be received no later than 90 days after the proposal due date. An application lacking the required IACUC certification 90 days after the proposal due date will be considered incomplete and may be returned to the applicant without review.

NSBRI will require current IACUC certification prior to each year's award.

<u>Duration of Proposed Research</u> – Proposals may be submitted for a duration of one to four years of funding, with an assumed start date of February 1, 2004.

<u>Special Ground Facilities</u> – A variety of special ground research capabilities, including centrifuge facilities, bed rest facilities, etc., are available for use by investigators submitting proposals in response to this NRA. Interested investigators are referred to the *Space Life Sciences Ground Facilities Information Package* for instructions on how to incorporate the use of these facilities into a proposal (see <a href="http://research.hq.nasa.gov/code\_u/nra/current/NRA-03-OBPR-04/index.html/">http://research.hq.nasa.gov/code\_u/nra/current/NRA-03-OBPR-04/index.html/</a>). Investigators must include the cost of using these facilities in their proposal.

Special Travel and Reporting Requirements – Principal Investigators selected in response to this NRA will be expected to attend two research team meetings, each of two days duration, per year at a location to be determined, as well as one general investigator workshop or retreat per year in the Houston area. Budgets should reflect the costs associated with these meetings and should include a statement indicating that this travel is a special requirement. Selected investigators will become part of the NSBRI's research program and will be expected to provide an annual progress report. Progress is reviewed by the NSBRI's Board of Scientific Counselors (BSC) and reported to NSBRI Management. In addition, investigators will be required to provide annual project information for inclusion in NASA's OBPR Program Tasks and Bibliography. The progress report and Task Book information will be collected electronically.

<u>Data Management Plan</u> – Most data collected through NSBRI support are required to be placed in a central Institute data archive. Investigators should plan to deliver their data to the NSBRI archive *as it is collected*, and should include the cost of such data archiving in their submitted proposal. If selected, a data management plan, including a list of the data products and a schedule for their delivery, must be prepared and submitted to the NSBRI. No additional costs should accompany this plan.

### V. Review and Selection Process

Investigators should refer to Appendix A, Section V, for a description of the overall NASA/NSBRI review and selection process.

The selection process will follow the sequence:

- 1. Review for scientific and technical merit
- 2. Review for programmatic relevance
- 3. Selection of Team Leaders and Team Leader projects
- 4. Selection of remaining proposals for funding

Elements of review and selection unique to the NSBRI are as follows:

NSBRI applications will be evaluated for scientific and technical merit and for the likelihood that the research proposed will have a significant impact on achieving the goals stated in this NRA. As discussed in Appendix A, the initial review will be carried out by an appropriate panel of experts who will discuss and provide a written critique of each proposal. The scientific or technical merit evaluation can be found in Appendix A, Section V of this Announcement. NSBRI proposals scoring in the competitive range will receive a second-level review by NSBRI BSC members. The BSC members will determine how well the research proposal fits with the research priorities enumerated in this Appendix and the Teams' Strategic Plans. These evaluations will be used for programmatic assessment and prioritization, including input from EAC members, newly selected Team Leaders (for those proposals being considered for selection after Team Leaders have been chosen), and NSBRI Management.

The programmatic relevance assessment will include an evaluation of how the proposed work will help achieve an appropriate balance of scientific and technical tasks required by the critical research issues outlined in the CPR. Assessment of the cost of a proposed effort includes consideration of the appropriateness of the costs and their relationship to available funds.

A set of selection recommendations will be developed by the EAC based on the merit review scores, team relevance, programmatic relevance, and costs. The most important element in the evaluation process is the merit review, which carries the highest weight in final evaluation and selection. The other factors are approximately equal in weight to each other. **Deficiencies in any one of these factors may prevent selection of a proposal.** Proposed selections will be coordinated between the Bioastronautics Research Division at NASA Headquarters and the NSBRI to ensure programmatic balance and elimination of duplicate efforts. Final selections for funding of NSBRI proposals will be made by the NSBRI Director.

### **Team Leader Application and Selection**

Do not put any reference to your interest in being a Team Lead in your proposal. For information only, the following is provided.

To be considered for NSBRI Team Leadership positions, the following criteria must be met in the separate selection process:

- 1. An application for a Team Leadership position must be submitted using EPSS;
- 2. A separate research proposal in response to this appendix of this NRA must be submitted;
- 3. Proposal must receive a peer review score that places it within the competitive range for scientific/technical merit; and
- 4. Proposal must be clearly relevant to the NSBRI research team to which applicant is applying.

For applications that meet these four criteria, the NSBRI EAC will carry out the following:

- 1. Consider the peer review panel comments on the scientific and technical merit of each qualifying proposal;
- 2. Consider the comments of the BSC concerning team relevancy;
- 3. Evaluate the merits of Team Leader applicants using the Team Leadership criteria identified in the Call for Candidates Solicitation; and
- 4. Based on the aforementioned criteria 1-3, make recommendations to the NSBRI Director.

The NSBRI Director will make nominations for Team Leadership positions, which require approval by the NSBRI Board of Directors. Selection of Team Leader projects will be made by the NSBRI Director in coordination with NASA.

Research proposals from unsuccessful Team Leader applicants will be returned with the other proposals for potential selection for funding.

Original signed by_	
	Bobby R. Alford, M.D., Chairman of the Board and CEO
	NSBRI

## CERTIFICATION REGARDING DEBARMENT, SUSPENSION, AND OTHER RESPONSIBILITY MATTERS

### PRIMARY COVERED TRANSACTIONS

This certification is required by the regulations implementing Executive Order 12549, Debarment and Suspension, 14 CFR Part 1269.

### A. The applicant certifies that it and its principals:

- (a) Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal department or agency;
- (b) Have not within a three-year period preceding this application been convicted or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or Local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;
- (c) Are not presently indicted for or otherwise criminally or civilly charged by a government entity (Federal, State, or Local) with commission of any of the offenses enumerated in paragraph A.(b) of this certification; and
- (d) Have not within a three-year period preceding this application/proposal had one or more public transactions (Federal, State, or Local) terminated for cause or default; and
- B. Where the applicant is unable to certify to any of the statements in this certification, he or she shall attach an explanation to this application.
- C. Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion Lowered Tier Covered Transactions (Subgrants or Subcontracts)
  - a) The prospective lower tier participant certifies, by submission of this proposal, that neither it nor its principles is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department of agency.
  - b) Where the prospective lower tier participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal.

### CERTIFICATION REGARDING LOBBYING

As required by S 1352 Title 31 of the U.S. Code for persons entering into a grant or cooperative agreement over \$100,000, the applicant certifies that:

- (a) No Federal appropriated funds have been paid or will be paid by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, in connection with making of any Federal grant, the entering into of any cooperative, and the extension, continuation, renewal, amendment, or modification of any Federal grant or cooperative agreement;
- (b) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting an officer or employee of any agency, Member of Congress, an or an employee of a Member of Congress in connection with this Federal grant or cooperative agreement, the undersigned shall complete Standard Form LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.
- (c) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subgrants, contracts under grants and cooperative agreements, and subcontracts), and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by S1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

# CERTIFICATION OF COMPLIANCE WITH THE NASA REGULATIONS PURSUANT TO NONDISCRIMINATION IN FEDERALLY ASSISTED PROGRAMS

The (Institution, corporation, firm, or other organization on whose behalf this assurance is signed, hereinafter called "Applicant") hereby agrees that it will comply with Title VI of the Civil Rights Act of 1964 (P.L. 88-352), Title IX of the Education Amendments of 1962 (20 U.S. 1680 et seq.), Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S. 794), and the Age Discrimination Act of 1975 (42 U.S. 16101 et seq..), and all requirements imposed by or pursuant to the Regulation of the National Aeronautics and Space Administration (14 CFR Part 1250) (hereinafter called "NASA") issued pursuant to these laws, to the end that in accordance with these laws and regulations, no person in the United States shall, on the basis of race, color, national origin, sex, handicapped condition, or age be excluded from participating in, be denied the benefits of, or be otherwise subjected to discrimination under any program or activity for which the Applicant receives federal financial assistance from NASA; and hereby give assurance that it will immediately take any measure necessary to effectuate this agreement.

If any real property or structure thereon is provided or improved with the aid of federal financial assistance extended to the Applicant by NASA, this assurance shall obligate the Applicant, or in the case of any transfer of such property, any transferee, for the period during which the real property or structure is used for a purpose for which the federal financial assistance is extended or for another purpose involving the provision of similar services or benefits. If any personal property is so provided, this assurance shall obligate the Applicant for the period during which the federal financial assistance is extended to it by NASA.

This assurance is given in consideration of and for the purpose of obtaining any and all federal grants, loans, contracts, property, discounts, or other federal financial assistance extended after the date hereof to the Applicant by NASA, including installment payments after such date on account of applications for federal financial assistance which were approved before such date. The Applicant recognized and agrees that such federal financial assistance will be extended in reliance on the representations and agreements made in this assurance, and the United States shall have the right to seek judicial enforcement of this assurance. His assurance is binding on the Applicant, its successors, transferees, and assignees, and the person or persons whose signatures appear below are authorized to sign on behalf of the Applicant.

# INSTRUCTIONS FOR RESPONDING TO NASA RESEARCH ANNOUNCEMENTS (MAY 2002)

### (a) General.

- (1) Proposals received in response to a NASA Research Announcement (NRA) will be used only for evaluation purposes. NASA does not allow a proposal, the contents of which are not available without restriction from another source, or any unique ideas submitted in response to an NRA to be used as the basis of a solicitation or in negotiation with other organizations, nor is a preaward synopsis published for individual proposals.
- (2) A solicited proposal that results in a NASA award becomes part of the record of that transaction and may be available to the public on specific request; however, information or material that NASA and the awardee mutually agree to be of a privileged nature will be held in confidence to the extent permitted by law, including the Freedom of Information Act.
- (3) NRAs contain programmatic information and certain requirements which apply only to proposals prepared in response to that particular announcement. These instructions contain the general proposal preparation information which applies to responses to all NRAs.
- (4) A contract, grant, cooperative agreement, or other agreement may be used to accomplish an effort funded in response to an NRA. NASA will determine the appropriate award instrument. Contracts resulting from NRAs are subject to the Federal Acquisition Regulation and the NASA FAR Supplement. Any resultant grants or cooperative agreements will be awarded and administered in accordance with the NASA Grant and Cooperative Agreement Handbook (NPG 5800.1).
- (5) NASA does not have mandatory forms or formats for responses to NRAs; however, it is requested that proposals conform to the guidelines in these instructions. NASA may accept proposals without discussion; hence, proposals should initially be as complete as possible and be submitted on the proposers' most favorable terms.
- (6) To be considered for award, a submission must, at a minimum, present a specific project within the areas delineated by the NRA; contain sufficient technical and cost information to permit a meaningful evaluation; be signed by an official authorized to legally bind the submitting organization; not merely offer to perform standard services or to just provide computer facilities or services; and not significantly duplicate a more specific current or pending NASA solicitation.
- (b) **NRA-Specific Items.** Several proposal submission items appear in the NRA itself: the unique NRA identifier; when to submit proposals; where to send proposals; number of copies required; and sources for more information. Items included in these instructions may be supplemented by the NRA.

(c) The following information is needed to permit consideration in an objective manner. NRAs will generally specify topics for which additional information or greater detail is desirable. Each proposal copy shall contain all submitted material, including a copy of the transmittal letter if it contains substantive information.

### (1) Transmittal Letter or Prefatory Material.

- (i) The legal name and address of the organization and specific division or campus identification if part of a larger organization;
- (ii) A brief, scientifically valid project title intelligible to a scientifically literate reader and suitable for use in the public press;
- (iii) Type of organization: e.g., profit, nonprofit, educational, small business, minority, women-owned, etc.;
- (iv) Name and telephone number of the principal investigator and business personnel who may be contacted during evaluation or negotiation;
- (v) Identification of other organizations that are currently evaluating a proposal for the same efforts;
  - (vi) Identification of the NRA, by number and title, to which the proposal is responding;
  - (vii) Dollar amount requested, desired starting date, and duration of project;
  - (viii) Date of submission; and
- (ix) Signature of a responsible official or authorized representative of the organization, or any other person authorized to legally bind the organization (unless the signature appears on the proposal itself).
- (2) **Restriction on Use and Disclosure of Proposal Information.** Information contained in proposals is used for evaluation purposes only. Offerors or quoters should, in order to maximize protection of trade secrets or other information that is confidential or privileged, place the following notice on the title page of the proposal and specify the information subject to the notice by inserting an appropriate identification in the notice. In any event, information contained in proposals will be protected to the extent permitted by law, but NASA assumes no liability for use and disclosure of information not made subject to the notice.

### **Notice**

### Restriction on Use and Disclosure of Proposal Information

The information (data) contained in [insert page numbers or other identification] of this proposal constitutes a trade secret and/or information that is commercial or financial and confidential or privileged. It is furnished to the Government in confidence with the understanding that it will not, without permission of the offeror, be used or disclosed other than for evaluation purposes; provided, however, that in the event a contract (or other agreement) is awarded on the basis of this proposal the Government shall have the right to use and disclose this information (data) to the extent provided in the contract (or other agreement). This restriction does not limit the Government's right to use or disclose this information (data) if obtained from another source without restriction.

(3) **Abstract.** Include a concise (200-300 word if not otherwise specified in the NRA) abstract describing the objective and the method of approach.

### (4) **Project Description.**

- (i) The main body of the proposal shall be a detailed statement of the work to be undertaken and should include objectives and expected significance; relation to the present state of knowledge; and relation to previous work done on the project and to related work in progress elsewhere. The statement should outline the plan of work, including the broad design of experiments to be undertaken and a description of experimental methods and procedures. The project description should address the evaluation factors in these instructions and any specific factors in the NRA. Any substantial collaboration with individuals not referred to in the budget or use of consultants should be described. Subcontracting significant portions of a research project is discouraged.
- (ii) When it is expected that the effort will require more than one year, the proposal should cover the complete project to the extent that it can be reasonably anticipated. Principal emphasis should be on the first year of work, and the description should distinguish clearly between the first year's work and work planned for subsequent years.
- (5) **Management Approach.** For large or complex efforts involving interactions among numerous individuals or other organizations, plans for distribution of responsibilities and arrangements for ensuring a coordinated effort should be described.
- (6) **Personnel.** The principal investigator is responsible for supervision of the work and participates in the conduct of the research regardless of whether or not compensated under the award. A short biographical sketch of the principal investigator, a list of principal publications and any exceptional qualifications should be included. Omit social security number and other personal items which do not merit consideration in evaluation of the proposal. Give similar biographical information on other senior professional personnel who will be directly associated with the project. Give the names and titles of any other scientists and technical personnel associated substantially with the project in an advisory capacity. Universities should list the approximate number of students or other assistants, together with information as to their level of academic attainment. Any special industry-university cooperative arrangements should be described.

### (7) Facilities and Equipment.

- (i) Describe available facilities and major items of equipment especially adapted or suited to the proposed project, and any additional major equipment that will be required. Identify any Government-owned facilities, industrial plant equipment, or special tooling that are proposed for use. Include evidence of its availability and the cognizant Government points of contact.
- (ii) Before requesting a major item of capital equipment, the proposer should determine if sharing or loan of equipment already within the organization is a feasible alternative. Where such arrangements cannot be made, the proposal should so state. The need for items that typically can be used for research and non-research purposes should be explained.

### (8) Proposed Costs (U.S. Proposals Only).

(i) Proposals should contain cost and technical parts in one volume: do not use separate "confidential" salary pages. As applicable, include separate cost estimates for salaries and wages; fringe benefits; equipment; expendable materials and supplies; services; domestic and foreign travel; ADP expenses; publication or page charges; consultants; subcontracts; other miscellaneous identifiable direct costs; and indirect costs. List salaries and wages in appropriate organizational categories (e.g., principal investigator, other scientific and engineering professionals, graduate

students, research assistants, and technicians and other non-professional personnel). Estimate all staffing data in terms of staff-months or fractions of full-time.

- (ii) Explanatory notes should accompany the cost proposal to provide identification and estimated cost of major capital equipment items to be acquired; purpose and estimated number and lengths of trips planned; basis for indirect cost computation (including date of most recent negotiation and cognizant agency); and clarification of other items in the cost proposal that are not self-evident. List estimated expenses as yearly requirements by major work phases.
- (iii) Allowable costs are governed by FAR Part 31 and the NASA FAR Supplement Part 1831 (and OMB Circulars A-21 for educational institutions and A-122 for nonprofit organizations).
- (iv) Use of NASA funds--NASA funding may not be used for foreign research efforts at any level, whether as a collaborator or a subcontract. The direct purchase of supplies and/or services, which do not constitute research, from non-U.S. sources by U.S. award recipients is permitted. Additionally, in accordance with the National Space Transportation Policy, use of a non-U.S. manufactured launch vehicle is permitted only on a no-exchange-of-funds basis.
- (9) **Security.** Proposals should not contain security classified material. If the research requires access to or may generate security classified information, the submitter will be required to comply with Government security regulations.
- (10) **Current Support.** For other current projects being conducted by the principal investigator, provide title of project, sponsoring agency, and ending date.

### (11) Special Matters.

- (i) Include any required statements of environmental impact of the research, human subject or animal care provisions, conflict of interest, or on such other topics as may be required by the nature of the effort and current statutes, executive orders, or other current Government-wide guidelines.
- (ii) Proposers should include a brief description of the organization, its facilities, and previous work experience in the field of the proposal. Identify the cognizant Government audit agency, inspection agency, and administrative contracting officer, when applicable.

### (d) Renewal Proposals.

- (1) Renewal proposals for existing awards will be considered in the same manner as proposals for new endeavors. A renewal proposal should not repeat all of the information that was in the original proposal. The renewal proposal should refer to its predecessor, update the parts that are no longer current, and indicate what elements of the research are expected to be covered during the period for which support is desired. A description of any significant findings since the most recent progress report should be included. The renewal proposal should treat, in reasonable detail, the plans for the next period, contain a cost estimate, and otherwise adhere to these instructions.
- (2) NASA may renew an effort either through amendment of an existing contract or by a new award.

(e) **Length.** Unless otherwise specified in the NRA, effort should be made to keep proposals as brief as possible, concentrating on substantive material. Few proposals need exceed 15-20 pages. Necessary detailed information, such as reprints, should be included as attachments. A complete set of attachments is necessary for each copy of the proposal. As proposals are not returned, avoid use of "one-of-a-kind" attachments.

### (f) Joint Proposals.

- (1) Where multiple organizations are involved, the proposal may be submitted by only one of them. It should clearly describe the role to be played by the other organizations and indicate the legal and managerial arrangements contemplated. In other instances, simultaneous submission of related proposals from each organization might be appropriate, in which case parallel awards would be made.
- (2) Where a project of a cooperative nature with NASA is contemplated, describe the contributions expected from any participating NASA investigator and agency facilities or equipment which may be required. The proposal must be confined only to that which the proposing organization can commit itself. "Joint" proposals which specify the internal arrangements NASA will actually make are not acceptable as a means of establishing an agency commitment.
- (g) **Late Proposals.** Proposals or proposal modifications received after the latest date specified for receipt may be considered if a significant reduction in cost to the Government is probable or if there are significant technical advantages, as compared with proposals previously received.
- (h) **Withdrawal.** Proposals may be withdrawn by the proposer at any time before award. Offerors are requested to notify NASA if the proposal is funded by another organization or of other changed circumstances which dictate termination of evaluation.

### (i) Evaluation Factors.

- (1) Unless otherwise specified in the NRA, the principal elements (of approximately equal weight) considered in evaluating a proposal are its relevance to NASA's objectives, intrinsic merit, and cost.
- (2) Evaluation of a proposal's relevance to NASA's objectives includes the consideration of the potential contribution of the effort to NASA's mission.
- (3) Evaluation of its intrinsic merit includes the consideration of the following factors of equal importance:
- (i) Overall scientific or technical merit of the proposal or unique and innovative methods, approaches, or concepts demonstrated by the proposal.
- (ii) Offeror's capabilities, related experience, facilities, techniques, or unique combinations of these which are integral factors for achieving the proposal objectives.
- (iii) The qualifications, capabilities, and experience of the proposed principal investigator, team leader, or key personnel critical in achieving the proposal objectives.

- (iv) Overall standing among similar proposals and/or evaluation against the state-of-the-art.
- (4) Evaluation of the cost of a proposed effort may include the realism and reasonableness of the proposed cost and available funds.
- (j) **Evaluation Techniques.** Selection decisions will be made following peer and/or scientific review of the proposals. Several evaluation techniques are regularly used within NASA. In all cases proposals are subject to scientific review by discipline specialists in the area of the proposal. Some proposals are reviewed entirely in-house, others are evaluated by a combination of in-house and selected external reviewers, while yet others are subject to the full external peer review technique (with due regard for conflict-of-interest and protection of proposal information), such as by mail or through assembled panels. The final decisions are made by a NASA selecting official. A proposal which is scientifically and programmatically meritorious, but not selected for award during its initial review, may be included in subsequent reviews unless the proposer requests otherwise.

### (k) Selection for Award.

- (1) When a proposal is not selected for award, the proposer will be notified. NASA will explain generally why the proposal was not selected. Proposers desiring additional information may contact the selecting official who will arrange a debriefing.
- (2) When a proposal is selected for award, negotiation and award will be handled by the procurement office in the funding installation. The proposal is used as the basis for negotiation. The contracting officer may request certain business data and may forward a model award instrument and other information pertinent to negotiation.

# (1) Additional Guidelines Applicable to Foreign Proposals and Proposals Including Foreign Participation.

- (1) NASA welcomes proposals from outside the U.S. However, foreign entities are generally not eligible for funding from NASA. Therefore, unless otherwise noted in the NRA, proposals from foreign entities should not include a cost plan unless the proposal involves collaboration with a U.S. institution, in which case a cost plan for only the participation of the U.S. entity must be included. Proposals from foreign entities and proposals from U.S. entities that include foreign participation must be endorsed by the respective government agency or funding/sponsoring institution in the country from which the foreign entity is proposing. Such endorsement should indicate that the proposal merits careful consideration by NASA, and if the proposal is selected, sufficient funds will be made available to undertake the activity as proposed.
- (2) All foreign proposals must be typewritten in English and comply with all other submission requirements stated in the NRA. All foreign proposals will undergo the same evaluation and selection process as those originating in the U.S. All proposals must be received before the established closing date. Those received after the closing date will be treated in accordance with paragraph (g) of this provision. Sponsoring foreign government agencies or funding institutions may, in exceptional situations, forward a proposal without endorsement if

endorsement is not possible before the announced closing date. In such cases, the NASA sponsoring office should be advised when a decision on endorsement can be expected.

- (3) Successful and unsuccessful foreign entities will be contacted directly by the NASA sponsoring office. Copies of these letters will be sent to the foreign sponsor. Should a foreign proposal or a U.S. proposal with foreign participation be selected, NASA's Office of External Relations will arrange with the foreign sponsor for the proposed participation on a no-exchange-of-funds basis, in which NASA and the non-U.S. sponsoring agency or funding institution will each bear the cost of discharging their respective responsibilities.
- (4) Depending on the nature and extent of the proposed cooperation, these arrangements may entail:
  - (i) An exchange of letters between NASA and the foreign sponsor; or
  - (ii) A formal Agency-to-Agency Memorandum of Understanding (MOU).
- (m) Cancellation of NRA. NASA reserves the right to make no awards under this NRA and to cancel this NRA. NASA assumes no liability for canceling the NRA or for anyone's failure to receive actual notice of cancellation.

# Proposal Submission Frequently Asked Questions (FAQs) and Sample Forms

(Independent Investigator Research Projects Only)

The information provided here is in response to questions from investigators such as yourself. Additional information regarding submission procedures and requirements can be found in the research announcement to which you are responding, and at the NASA online proposal site:

http://proposals.hq.nasa.gov/proposal.cfm

### 1. What forms should I use when submitting a proposal?

Currently, the NASA proposal site does not support the uploading of information or forms other than the information gathered while completing the online cover page. Please complete the online cover page early in the process (you can always return and edit the cover page at any time up to the due date). After completing the cover page, any additional information you are required to provide or wish to provide can be submitted in hardcopy in any format you choose.

Please find included in this document several sample forms that you may use when providing additional information. A standard checklist of materials to include is also provided. Information outside of the online proposal cover page can be provided in any format you choose, as long as it adheres to the NRA requirements. Please reference the NRA for information on all material required when submitting your proposal. Please be aware that we ask for copies of the completed proposal package, not just the project description, and must **receive** the copies by the proposal due date. The additional information requested in the NRA does not count towards the 20 page limit of your project description.

### 2. Where does my authorizing official sign?

You must include your authorizing official as a team member. When you complete and print the proposal cover page, you will see signature blocks both for yourself and your authorizing official. You are required to submit one original signed (by both you and your authorizing official) cover page with your proposal hardcopies.

To be added as a team member to your proposal, the individual must be registered with the SYS-EYFUS system. If you try and add a team member and they are not found in the database, you must contact and have that individual register as a new SYS-EYFUS user. You will then be able to add them as a team member.

# 3. Who should I contact if I receive errors or have additional problems while using the NASA proposal site?

For technical support, please e-mail proposals@hq.nasa.gov or call 202-479-9376 (Monday to Friday 8 a.m.-6 p.m. EST/EDT).

### **CHECKLIST FOR PROPOSERS**

(Independent Investigator Research Projects Only)

Proposal Cover Page (completed online)
Response to previous reviews (if applicable)
Project Description
Biographical Sketches
Other Support
Facilities and Equipment Description
Summary Budget Form/Budget Justification
Detailed 12-Month Budget (for each year of support)
IRB or ACUC letter/form (if applicable)
Letters of Collaboration/Support (if applicable)
Appendices, if any

### (Independent Investigator Research Projects Only)

BIOGRAPHICA Provide the following informa Photocopy this page or follow to	tion for the key p						
NAME POSITION TITLE							
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training).							
INSTITUTION(S) AND LOCATION	DEGREE(S) (if applicable)	YEAR(S)	FIELD(S) OF STUDY				

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list, in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles, all authors, and complete references to all publications during the past three years, and to representative earlier publications pertinent to this application. If the list of publications in the last three years exceeds two pages, select the most pertinent publications. **DO NOT EXCEED TWO PAGES.** 

Form C

(Independent Investigator Research Projects Only)

# BUDGET FOR ENTIRE PROJECT PERIOD DIRECT COSTS ONLY

BUDGET CATEGORY TOTALS		1 <sup>st</sup> BUDGET PERIOD	ADDITIONAL YEARS OF SUPPORT REQUESTED			
			2 <sup>nd</sup>	3 <sup>rd</sup>	4 <sup>th</sup>	
PERSONNEL (Salary and						
Fringe Benefits) (Applicant organization only)						
(Applicant organ	mization only)					
SUBCONTR A	CTS					
SOBCONTRA	1015					
CONSULTAN	NT COSTS					
EQUIPMENT	Γ					
GLIDDI IEG						
SUPPLIES						
TED AXIEL						
TRAVEL	DOMESTIC					
	NON-DOMESTIC					
	•					
OTHER EXP	ENSES					
TOTAL DIDE	CT COSTS FOR					
EACH PERIO						
TOTAL INDIR	RECT COSTS FOR					
EACH PERIO						
	CT + INDIRECT					
COSTS FOR E	CACH PERIOD					
TOTAL DIRE	CCT + INDIRECT C	OSTS FOR ENTIRE PR	OJECT			

### JUSTIFICATION FOR UNUSUAL EXPENSES:

### Form D

### (Independent Investigator Research Projects Only)

PERIOD	DGET FOR 12-MONTH BU DIRECT COSTS ONLY	DGET	FROM		THROUGH	
	m for each year of grant	<u> </u>		1		
support requested	1	ELD	IDDIG AMOI		N IDODI	TD.
PERSONNEL (Applicant Organ	ization Only)	FUI	IDING AMOU	INT REQ	UESTE	ED .
NAME	ROLE IN PROJECT	EFFORT ON PROJECT	SALARY FRINGE BENEFITS			TOTALS
	Principal Investigator					
SUBTOTALS	<b></b>					
SUBCONTRACT	ΓS					
CONSULTANT	COSTS					
EQUIPMENT (Itemize; use additional sheet if needed)						
SUPPLIES (Item	ize by category; use additional	sheet if needed	)			
TRAVEL	DOMESTIC					
	NON-DOMESTIC					
OTHER EXPENS	SES (Itemize by category; use	additional sheet	if needed)			
TOTAL DIREC	T COSTS FOR FIRST 12-M	ONTH BUDG	ET PERIOD			
INDIRECT COS	STS FOR FIRST 12-MONTH	H BUDGET PE	RIOD			
TOTAL COST I	FOR FIRST 12-MONTH BU	DGET PERIO	D			

### **OTHER SUPPORT**

(Independent Investigator Research Projects Only)

Please provide information regarding specific sources of other support for the principal investigator and each co-investigator (not consultants). This information should be provided separately for each individual in the format shown below. List all active support for an individual before listing pending support. Include the investigator's name at the top of each page and number pages consecutively.

NAME OF INDIVIDUAL ACTIVE/PENDING				
Project Number (Principal Investigator)	Dates of Approved/ Proposed Project	Percent Effort		
Source Title of Project (or Subproject)	Annual Direct Costs			
One-sentence description of project goals. (7	The major goals of this proje	ect are)		
Brief description of potential scientific or co	mmitment overlap with res	pect to this individual		
between this application and projects described above (summarized for each individual).				

### Form F

### CRITICAL PATH ROADMAP (CPR) FORM

(Independent Investigator Research Projects and NSBRI Team Research Projects)

Hypotheses	Risk Number (from Critical Path Roadmap)	Critical Question Number (from Critical Path Roadmap)	Critical Question (from Critical Path Roadmap)	Specific Aim